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Design and Analysis of a Volume Adjustable Transtibial Prosthetic Socket for Pediatric Amputees in Developing Countries

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Design and Analysis of a Volume Adjustable Transtibial Prosthetic Socket for Pediatric Amputees in Developing Countries

by

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Abstract

Design and Analysis of a Volume Adjustable Transtibial Prosthetic Socket for Pediatric Amputees in Developing Countries

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The University of Texas at Austin, 2009

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For pediatric amputees in developing countries, where characteristically rapid growth of children is compounded by a lack of medical services, maintaining proper socket fit is a challenging but necessary endeavor. A socket design that adjusts for radial and longitudinal growth will allow patients to wear the same socket for a longer period of time saving them the expense of subsequent fittings and hardware. Manufacture of such a socket poses a challenge for contemporary manufacturing processes. Due to its ability to rapidly manufacture complex part geometries, Selective Laser Sintering (SLS) is particularly suited to this application. Several preliminary design concepts for a volume adjustable transtibial SLS prosthetic socket for pediatric amputees in developing countries have been generated. These current design concepts utilize fasteners such as ratchet hooks and threads. Results from design and validation of theoretical models of these fastener concepts are the focus of this thesis.

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Chapter 1: *Introduction*

Proper design of a prosthetic socket component is critically important to an amputee's comfort and mobility. This artificial limb component provides the primary interface between the residual limb and the remainder of the prosthesis. Therefore, any failure of the socket to perform this function restricts the ability of the prosthesis to increase the mobility of the user. In addition to misalignment and improper initial fittings, changes in the volume, both radial and longitudinal, of the patient's residual limb are a primary contributor to the degradation of proper socket fit. This risk of wearing a prosthetic socket with poor fit is greater for pediatric amputees who must balance the financial and logistical impact of replacing their socket with increased rates of volumetric change characteristic of growth. With limited availability of appropriate technology, those patients located in low-income countries are impacted even more by this difficulty of maintaining proper socket fit. A new socket design is therefore needed that provides a robust design that can be used for a greater period of time by adjusting to the volumetric changes inherent in normal pediatric growth patters both radially and longitudinally.

Manufacture of such a socket poses a challenge for contemporary fabrication technologies. Due to its ability to rapidly manufacture complex part geometries, Selective Laser Sintering (SLS) is particularly suited to this application. *This thesis therefore documents the process utilized in designing an adjustable transtibial (below knee) prosthetic socket design for pediatric amputees in developing countries*. In particular, the following stages of the design process are described:

- Customer needs analysis to understand the requirements of the socket design based on the needs of the focus user population.

- Concept generation illustrating the variety of possible solutions envisioned. In particular, the concept generation focused on fastener technology that enables quick alteration of socket dimensions.
- Concept screening based on criteria developed during the customer needs analysis to identify the best concepts for further development.
- Preliminary embodiment of selected fastener concepts, including analytical models and testing of physical proof-of-concept models.

The thesis ends with a critical evaluation of the research and recommendations for future work.

Chapter 2: *Background*

Prosthetic Sockets

Limb amputation can be a life-altering event that requires special attention. Individuals with limb amputations are often faced with issues including decreased mobility, increased energy expenditure, negative social stigmas, added medical expenses, or limited career choices. These amputations can be the result of trauma, disease, or congenital defect (*Limb Loss*, 2009; Cummings & Kapp, 1992; Dillingham, Pezzin, & MacKenzie, 2002). Efforts, therefore, over the last few decades have focused on designing artificial limbs to fulfill the needs of 1.7 million people with limb loss in the United States alone and the nearly thirty million anticipated by 2010 in developing countries (*Limb Loss*, 2009; *Guidelines,* 2005). The most common type of amputation, making up 23.95% percent of both upper and lower limb amputations in the United States, is the below knee, or transtibial, amputation and is the focus of this research (Dillingham et al., 2002).

Unlike developed countries where the primary reason for amputation is diabetes, prosthetists in developing countries treat a larger percentage of cases where trauma is the reason for amputation, 35.7% in developing countries compared to 17% in developed (Dillingham et al., 2002; Ogeng'o et al., 2009, Table 1). These amputations are often the result of a vehicle, work or military accident. As a result, a younger population, with an average age of 29.2 years, is common in developing countries where the use of poor quality or recycled components is often not capable of supplying the needs of the amputee population (Ogeng'o et al., 2009). In comparison, most patients surveyed in the United States were between the ages of 19-44 years rather than 10-19 years as in developing countries (Dillingham et al., 2004; Ogeng'o et al., 2009). These patients therefore, regardless of location, require the use of a mobility aid, referred to as a prosthesis, due to limb loss commonly.

Cause	Developed Countries	Developing countries
Congenital Limb Difference	Use of thalidomide by mother during pregnancy and other unknown causes. (1%)	Relatively unknown causes, genetic (20%)
Disease	Diabetes Mellitus or other peripheral vascular diseases and cancer. (82%)	Polio, malignancy of bone or joint (44.3%)
Trauma	Motor vehicle accident, workplace injury, war (17%)	Landmine accident, Hippo bite, workplace injury, war, surgery complications (35.7%)

Table 1: Causes of Amputation for Developed and Developing countries (Dillingham et al., 2002; Ogeng'o, Obimbo, & King'ori, 2009)

1. Description of Prosthetic Limb

Though the quality can differ greatly, the solutions available to amputees around the world are all based on a basic lower limb prosthetic design. For above knee lower limb amputee, it is common to find, in addition to the socket and its suspension system, a knee, shank (pylon), ankle, and foot component included in the prosthetic device. As a transtibial amputee has an intact biological knee joint on the residual limb, the number of required artificial limb components reduces to the socket, shank (pylon), and ankle/foot components (Figure 1).

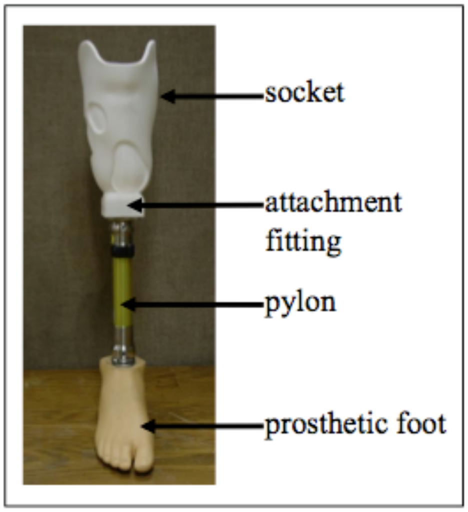

Figure 1: Basic Lower Limb Prosthetic Components (Photograph courtesy of The University of Texas Health Science Center in San Antonio)

As a unit, the primary function of an artificial limb is to replace the motor functions lost due to amputation. This functionality cannot be achieved without an interface between the residual limb and the artificial limb. The socket component provides this interface and is the focal point of this research.

2. Evolution of Prosthesis Design

The manufacturing technologies and materials available have largely limited the quality of prosthetic interfaces designed throughout history. The simplest solution to limb loss is the use of crutches or canes to help increase mobility. Early artificial limb designs were simple suspension belts with a cushion to support the residual limb built into a wooden frame. These were often referred to as 'peg legs' and are still common in low-income regions today. Later, exoskeleton style sockets were developed using the same skills required to manufacture armor (Figure 2). The resulting sockets provided basic support but lacked the proper fit later determined to be necessary. (Gutfleisch, 2003)

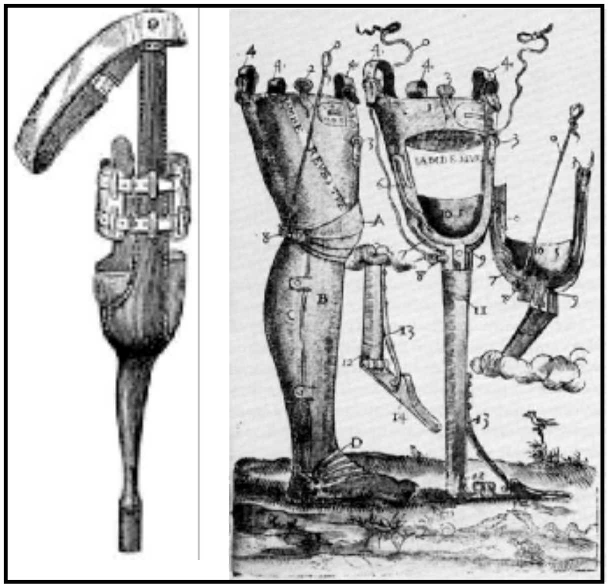

Figure 2: Early Transtibial Prosthetic Limb Designs (Gutfleisch, 2003)

3. State of the Art

More contemporary designs use modern engineering materials and manufacturing processes such as plastics or reinforced carbon fiber and Rapid Manufacturing (Gutfleisch, 2003; Rogers et al., 2007; Trower, 2006). These modern socket designs also utilize advancements made in understanding appropriate socket fit (Trower, 2006).

As the socket is the primary interface that distributes loads from the prosthesis to the residual limb, the method used to distribute these loads is critical to patient comfort and the quality of the socket fit. There are three primary schools of thought governing proper weight distribution in a prosthetic socket. The primary transition from early socket designs was the shift to total residual limb contact in the socket. The first of these socket designs implementing this limb contact, introduced in 1959, is the Specific Weight Bearing socket. This socket design is based on the thought that specific areas of the residual limb are capable of supporting greater amounts of weight based on higher pain tolerance levels. Particularly well known in this category is the Patella Tendon Bearing

(PTB) socket that uses the patella tendon as the primary weight bearing structure (Figure 3).

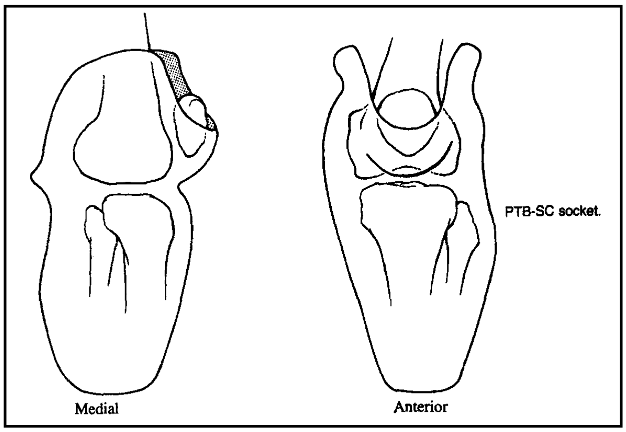

Figure 3: Patella Tendon Bearing Socket Design (Fergason, J. & Smith, D. G.1999)

These sockets often require significant manufacturing skill by prosthetists who manually modify the socket shape to provide increased/decreased contact based on locations identified through gait-based observations on a patient-by-patient basis for weight bearing. An alternative to the total contact specific weight bearing theory is the Total Surface weight Bearing (TSB) theory. Manufactured in much the same way as a PTB socket, this theory however assumes a more uniform distribution of weight bearing over the residual limb. The third major socket design theory to be discussed here is based on fluid dynamics and lacks distinctive weight bearing structures such as those used in PTB and TSB sockets (Figure 4).

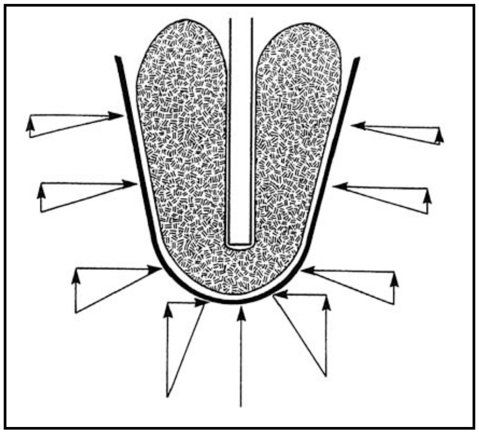

Figure 4: Pressure Distribution of Hydrostatic Socket (Fergason & Smith, 1999)

This Hydrostatic Socket fit is often achieved by applying a uniform pressure to the surface of the residual limb prior to casting to obtain the proper shape for the interior of the socket. Another method used to obtain the hydrostatic fit is the use of urethane or silicone liners that conform to the shape of the residual limb to redistribute the surface pressure. (Fergason, & Smith, 1999). More common is a blending of the PTB and TSB style socket designs (Trower, 2006).

In order to manufacture a socket using one of these weight distribution methods for a particular patient, a surface profile of the residual limb is needed for customization. Traditionally this is obtained using a plaster casting method. However, advancements in computer aided design (CAD) have been applied to socket manufacturing to improve the models of the internal socket profile for the socket design desired by the prosthetist (Rogers et al., 2007; Trower, 2006). High-resolution limb scanners are available as well as software for manipulation of the scans to produce the internal contour of the socket fit desired. Additive Manufacturing (AM) technology has also been developed that manufacture sockets from these digital models. One additive manufacturing technology that has been used to fabricate prosthetic sockets is Selective Laser Sintering (SLS)

(Rogers et al., 2007). SLS, discussed in more detail later, is a layer based manufacturing process that produces customized complex parts directly from a 3D computer model.

4. Pediatrics

For children, similar fitting and prosthetic design techniques are implemented. The technology, however, must be modified to account for the more rapid neurologic development, muscle strength increase, skeletal alignment, height increase, center of gravity changes, and gait changes (Cummings, 2006). As a result of their normal growth patterns, new prostheses are required more frequently for children. Children under five years of age typically require a new prosthesis annually, biannually between 5 to 12 years, and then once every 3 or 4 years over 12 years of age (Cummings, 2006). In addition to replacement of the prosthesis, prosthetists recommend frequent clinic visits, as often as every three to five months, for follow up and adjustment of the prosthesis (Cumming & Kapp, 1992).

GENERAL CASE NEEDS

In spite of the advancements made in understanding socket fit and improving manufacturing technology, the issue of greatest concern to amputees continues to be lack of proper fit and comfort in their socket (Dillingham et al., 2004; Legro, et al., 1999; Pezzin et al., 2004; Trower, 2006). "Currently available components offer improved function and superior symmetry of gait…The focus on the features of these components sometimes has led, however, to neglect of the basic elements of prosthetic design-the fit and the alignment," (Trower, 2006). This lack of comfort and proper fit can often be attributed to a change in the shape of the residual limb that cannot be compensated for by existing prosthetic socket technology. This shape change is either the increase or decrease in volume of the residual limb, in both the longitudinal and radial directions, caused by a variety of factors.

1. **Shape Change**

Based on the age of the amputee, growth can account for significant volume change in the residual limb. According to the National Health Statistics Report in 2008, between the ages of two and twelve, girls will grow an average of 6.52 cm in height per year while boys will grow 6.28 cm per year. By the age of nineteen, children have largely stopped growing and may only increase by 0.1 cm per year. (McDowell, Fryar, Ogden, & Flegal, 2006) The tibia, whose length change has the greatest effect on changing the longitudinal fit of the prosthetic socket, can change on average 18.75 mm each year for boys between the ages of 10 and 15 (Smith & Buschang, 2005).

In addition to vertical growth, weight changes can also contribute to changes in the residual limb volume either positively or negatively. Due to the typically reduced physical lifestyle of amputees, weight gain beyond the norm for aging is not uncommon. Obesity occurred in 37.9% of transtibial, 48.0% of transfemoral and 64.2% of bilateral amputee subjects studied. (Kurdibaylo, 1996) This weight gain causes an increase in the volume of the residual limb that must fit inside the patient's socket. For children, normal weight gain must also be accounted for in the socket design. From the ages of 2 to 10, an average increase of 3.65 kg/year for girls and 3.25 kg/year for boys is not uncommon (McDowell et al., 2006).

Another period where volume changes are prevalent is during postsurgical maturation. Studies have reported that the maturation process is often accelerated by early ambulation. During the maturation period, the volume of the residual limb can change as much as -8% to +2% depending on the method used to encourage shrinkage

(Golbranson et al., 1988). However, this is often a hindrance to early ambulation due to the cost of manufacturing multiple sockets during the maturation period where the residual limb volume is unstable. These postsurgical volume changes are often the result of either edema, fluid retention that causes swelling, or muscle atrophy in the residual limb (Golbranson et al., 1988). As a result, a stable volume measurement is difficult to obtain in order to manufacture a single properly fitting socket, and multiple fittings or volume adjustable sockets are needed.

Once the residual limb has reached maturity, volume fluctuations are not as extreme but are still noticeable in adults. Short term volume changes due to movement of fluid in the residual limb can occur. Removal of the socket after use can allow an increase in volume between 2.4% and 10.9% (Zachariah, Saxena, Furgason, & Sanders, 2004). In a comparison of suction and vacuum suspension systems, Board reports a decrease in volume in the suction suspension of 6.5% following walking for 30 minutes while the vacuum system increased in volume 3.7% (Board, Street, & Caspers, 2001).

2. Impact of Poor Fit

In the event a patient loses the proper fit of their residual limb in their prosthetic socket due to one or a combination of the factors described above, there are several possible negative consequences patients typically encounter. Limb volume can vary -11% to 7% in a single day due to changing activity level or weight. However, volume changes of only 3% to 5% can cause users to have difficulty putting on their prosthetic socket (Fernie & Holiday, 1982). The most common problem amputees encounter with an improperly fitting socket is the occurrence of pressure induced sores. Ulcers, irritations, inclusion cysts, calluses, and verrucous hyperplasia account for 79.5% of skin problems documented in a survey of 337 lower limb amputees (Dudek, Marks, & Marshall, 2006).

Similar to running shoes, the environment created by the residual limb inside the socket provides the elements necessary to produce surface wounds such as blisters or ulcerations (Backus, 2005). This environment provides the heat from the body and friction, pressure, and moisture that couple with an improperly positioned socket to produce sores. If the residual limb reduces in volume due to factors such as muscle atrophy or the socket is incorrectly fitted, a phenomenon called “pistoning” can occur. In pistoning, the residual limb volume reduces to such an extent that the limb moves relative to the socket during gait causing a piston-like motion within the socket. This can cause blisters to form as well as milking of the residual limb that draws fluid to the distal end causing, in the more extreme cases, verrucous hyperplasia (Beil & Street, 2004; Backus, 2005). In addition to forming sores on the residual limb, an improperly fitted socket can also cause the remainder of the socket to fail to function as originally designed.

If the socket reduces in volume and the residual limb is allowed to move relative to the socket, the alignment of the prosthesis can be altered, forcing the patient to adopt an improper gait pattern that can cause strain in the remainder of the sound body (Backus, 2005). Poor alignment can also cause an increase in oxygen consumption and therefore energy expenditure for the amputee (Schmalz, Blumentritt, & Jarasch, 2002). Misalignment can increase the stresses at the knee as well as redistribute socket pressure profiles (Blumentritt, Schmalz, Jarasch, & Schneider, 1999; Sanders, Bell, Okumura, & Dralle, 1998). These possible injuries have motivated the design of a variety of volume compensation options aiming to provide full functionality to the user.

3. Existing Solutions for Volume Compensation

Several options are currently available that attempt to compensate for volumetric changes in the residual limbs of children and adults.

Children

For children, the simplest method used for volume compensation is the addition/removal of liners or socks. The thickness of these inserts can be modified to adjust for radial growth based on the specific needs of the patient. Another insert based adjustment for radial growth is the use of ‘slip’ or ‘triple wall’ sockets. These sockets are manufactured with a socket layer that can be removed when the socket becomes too tight. In order to accommodate longitudinal growth, prosthetists use pads that are inserted into the distal end of the socket during initial fitting and then replaced with thinner pads as the patient grows. These pads provide cushioning in the socket as well as space for growth. In addition to these, suspension systems can be designed with adjustability for growth. (Cumming & Kapp, 1992)

Adults

As adults have stopped growing longitudinally, most volumetric change experienced in the mature residual limb is due to radial changes from fluctuations in weight. For more immediate location specific volume compensation, inserts are common. These inserts are often gel bladders that in some cases are actively actuated to regulate socket fit (Sanders & Cassisi, 2001; Greenwald, 2003). Another technique for accommodating location specific volume change is the use of a ‘flexible’ socket wall. An example of this is the use of compliant springs in the wall of a Selective Laser Sintered prosthetic socket designed by Rogers, et al. at The University of Texas at Austin (2007). As with children, socks and liners can be added or removed to accommodate a more uniform volume change. The suspension system used by the patient can also contribute to the volume compensation ability of the prosthesis. Research has shown that systems like the Harmony Vacuum Assisted Suspension System (Harmony VASS) manufactured by Otto Bock (www.ottobockus.com) can help reduce daily volumetric changes (Board et al., 2004). This is due to the assistance provided by the vacuum being drawn on the residual limb to maintain proper fluid flow in the residuum. Another method used to accommodate shape changes, particularly post surgical, is the use of a socket design consisting of five "plates" that are fitted together using supports and Velcro straps (Sathishkumar et al., 2004). This sort of device can be adjusted for reductions in size due to atrophy and swelling as well as increases in size due to body mass increase.

4. Shortfalls of Existing Technologies

Though some solutions are available, socket fit continues to be a point of interest to amputees and prosthetists. The greatest problem with the existing socket designs is that they are only capable of accommodating growth up to the maximum allowable volume for which the socket was designed. Most of the readily available devices are primarily designed for volume loss, such as inserts, rather than growth. These devices can increase the complexity of the prosthetic by adding additional separate components that must be maintained. Sockets are therefore oversized and then filled to accommodate future growth. However as additional volume loss occurs, this means that insecure padding that has been added compromises the strength of the interface. Most available volume compensation devices are also only capable of adjusting for either radial or longitudinal growth, but not both.

DEVELOPING COUNTRIES

Unfortunately, due to the lack of resources, technology available in developing countries has not improved at the same rate as that in developed countries. From personal observations at clinics in both Sierra Leone and Kenya, Africa, patients are often provided with technology that has regressed to early prosthetic limb designs. For a variety of reasons, patients are often found using only crutches or canes rather than actual prosthetic limbs. When patients are able to obtain prosthetic limbs they are usually of the simplest form, often using recycled components. The use of recycled components can mean that an active youth may be using a component intended for an elderly patient and is therefore unable to provide the necessary level of functionality based on the patient's activity level.

When components, particularly sockets, are manufactured, the quality of the fit is dependent on the skill level and training of the technician. By 2010, the World Health Organization (WHO) estimates that the number of prostheses demanded in developing countries will reach thirty million (*Guidelines,* 2005). To fulfill this demand, more than 40,000 additional personnel are needed *(Guidelines,* 2005). However, the number of prosthetic and orthotic facilities in several African countries is less than one per two to four million inhabitants. This is significantly lower than the one prosthetist per 200,000 - 400,000 individuals common in developed countries. Those facilities that do exist however, are often understaffed and lack the equipment and material necessary to maintain production rates of facilities in developed countries. Those prostheses that are manufactured tend to be of poor quality as a result of insufficient training, equipment, and materials. (*Disability*, 1999)

To compound the issues of lack of adequately trained prosthetists and poor quality prosthetic components, patients themselves often have difficulty simply obtaining prostheses that are made available to them. Transportation often proves to be a hindrance to patients in need of prostheses. Due to the lack of resources and low population densities in rural areas, prosthetic services tend to be centralized to major cities and capitals. This means that many amputees in rural areas are unable to obtain prosthetic services due to the distances that must be traveled and the associated expenses. Finances are also a large barrier to amputees in developing countries. Low cost or donated prostheses are the primary source of prosthetic limbs in developing countries due to the lack of funds. (*Disability*, 1999) This tends to eliminate the use of devices such as the Otto Bock Harmony VASS that can cost upwards of $5000 to $50,000 dollars (Turner, 2009).

ADDITIVE MANUFACTURING

Due to the complex contours of the residual limb and the need for customization of prosthetic sockets, Additive Manufacturing (AM) is particularly suited for this application. Computer Aided Design and Computer Aided Manufacture (CAD/CAM) of prosthetic sockets has been used for several decades, including uses in developing countries (Smith & Burgess, 2001; Walsh, Lancaster, Faulkner & Rogers, 1989). Traditionally, scans of the residual limb are obtained using 3D laser scanners and the resulting surface contours are then modified by the prosthetist using CAD software. These surface contours are sent to Computer Numerical Controlled (CNC) milling machines that mill a positive mold of the socket to be manufactured. The final socket is made from the mold by vacuum forming with plastic, such as polypropylene, or building with reinforced carbon fiber (Bosker, 2008). Other methods mill the socket directly from the socket material and skip the molding step (Walsh et al., 1989). The use of Additive Manufacturing will further reduce the number of steps required for the prosthetist and, more importantly, enable increased complexity and functionality in the design of the socket.

1. Description of SLS

Selective Laser Sintering is an Additive Manufacturing technology that was first developed by Carl Deckard at The University of Texas at Austin during the 1980's (Deckard, 1989). SLS is a layer-based technology that manufactures parts directly from a

3D solid model out of a variety of powdered raw materials. In using this technology, an engineer first models the desired part using solid modeling software, and then sends the model to the SLS machine in a special file format, the so-called STL file. This file describes surfaces of the 3D part to be manufactured as a set of non-overlapping triangular surfaces. The SLS software then essentially slices the part file into layers to be built in the SLS machine. This research used the Vanguard HiQ/HS SLS machine manufactured by 3D Systems (Rock Hill, SC). In one cycle of the process, a roller first deposits a layer of raw material from a feed bin onto the preheated part bed. This material can be either a plastic material such as DuraForm PA® (Nylon 12) or a metal-based material such as LaserFormTM A6, both manufactured by 3D Systems. After powder deposition, a CO_2 laser scans the surface of the powder to melt the powder in the areas contained in the current part layer. After scanning, the part bed lowers and the appropriate feed bin raises a single layer thickness and the cycle restarts from the opposite side of the machine. When all layers of the part have been sintered, the part bed is allowed to cool and then the part is broken out of the unsintered powder that acts as a support during the building process.

2. AM of Prosthetics

Building on the traditional use of CAD/CAM to produce a prosthetic socket, additive manufacturing has been previously applied to prosthetic socket manufacturing. Early SLS prosthetic sockets were manufactured at The University of Texas at Austin. These sockets were designed to provide passive compliant regions for pressure relief in the socket wall (Faustini et al., 2005; Faustini, Neptune & Crawford, 2006; Faustini et al., 2006; Rogers et al., 2007). Relying on the design flexibility of SLS, the compliant features evolved from simple thin wall designs to cantilevers to more complex spiral spring designs.

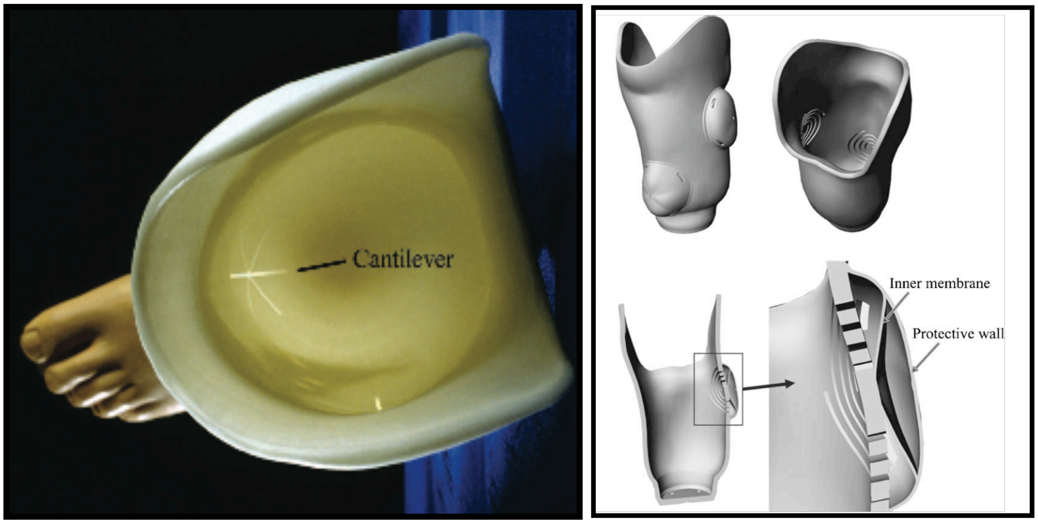

Figure 5: Previous SLS Compliant Sockets from UT Austin (Faustini, Neptune & Crawford, 2006; Rogers et al. 2007)

The Squirt Shape Prosthetic Socket developed at Northwestern University (Evansville, IL) has also utilized AM (Rolock, 2007; Rovik & Childress, 1994; Herbert, Simpson, Spence & Ion, 2005). The Squirt Shape process is similar to Fused Deposition Modeling (FDM), in which a plastic filament is heated and extruded through a nozzle moved by a three-axis table to build a part in circular layers. Similarly, Ng, Lee, and Goh used FDM equipment (available from Stratasys, Inc.®, Eden Prairie, MN) to manufacture a prosthetic socket (2002). The socket is built from essentially a single continuous bead of melted plastic extruded along the desired contour generated using CAD software from 3D scans of the patient’s residual limb. This socket has reportedly passed the ISO 10328 standard.

3D printing, a technique where powder layers are sprayed with a binder by an inkjet printer type head, has also been used to manufacture prosthetic sockets (Herbert et al., 2005). However the strength and durability of these sockets has not been established.

PROBLEM STATEMENT

A new lower limb transtibial prosthetic socket design is therefore needed that can satisfy the volume compensation requirements of the developing world's pediatric amputee population. In theory, this same design could easily be modified to aid amputees all over the world. This thesis is a record of the initial stages in the design of a transtibial prosthetic socket, to be manufactured using Selective Laser Sintering, for pediatric patients in developing countries that accommodates long term volumetric changes in the residual limb. The initial stages of the design of this prosthetic socket consist of the design and analysis of volume compensation mechanisms for both radial and longitudinal volumetric changes.

POTENTIAL IMPACT

A successfully designed volume-compensating socket has the potential to positively impact amputee communities in developing countries. The greatest benefit to the amputee community is the potential for increased longevity of socket usage each day as well as the total life of the socket. This increased lifespan helps to reduce the required number of additional fittings. This means that the number of visits patients must make to the clinic can be reduced, allowing prosthetists to work with the patient's culture by adjusting to what they are capable of rather than forcing them into our framework of more frequent visits and the associated costs (Pearlman et al., 2008). The use of CAD software and SLS also provides a more precise model of the residual limb and therefore improved socket fit that can reduce pressure related sores, resulting increased comfort

(Rogers et al., 2007). This volume compensation can also allow prosthetists to begin fitting patients earlier after amputation allowing ambulation to aid the maturation process (van Velzen, Nederhand, Emmelot & Ijerman, 2005).

Chapter 3: *Proposed Solution Requirements*

Sources for Customer Needs Analysis

Designing a transtibial prosthetic socket manufactured using SLS for accommodation of growth for pediatric amputees in developing countries requires certain considerations to ensure that the customers' needs are appropriately addressed. The primary issue to be addressed in this design process is that the engineer cannot simply assume they understand what a user needs (Pollak, 2008; Otto & Wood, 2000). They must instead seek to discover the latent needs of the customer and make sure that their design solution addresses these needs. The best way of doing this is to be able to simply *ask* the patients what functions they would like in their prosthetic devices. Therefore, the sources used in this thesis to complete a customer needs analysis were selected to provide the best understanding of the customers' needs in light of this issue. These sources include a review of pertinent literature, personal experience at Prosthetic and Orthotic clinics in Kenya and Sierra Leone, Africa, as well as interviews with a certified prosthetist/orthotist. These sources were used to develop several design requirements for this project, including manufacturing, biomedical and biomechanical, adjustability, durability, and other user requirements.

Personal Experience

Personal experience with prosthetic limb design and manufacture, prior to the current research, stems from participation in a senior capstone research program, LeTrourneau Engineering Global Solutions (LEGS), now LeTourneau Empowering Global Solutions, at LeTourneau University (www.legsresearch.org, Longview, Texas). This program's mission was to:

> [D]esign, create, and test high-quality lower extremity artificial limbs (prostheses) for patients across the developing world, focusing on above-knee prostheses. These devices are designed to be inexpensive and maintenance free, improving gait while still meeting the manufacturing, rehabilitation, and cultural constraints of various international sites.

This program provided general knowledge of available prosthetic technology, patient needs, culturally appropriate designs, patient fitting and rehabilitation methods, and prosthetic manufacturing techniques during on-site clinic visits and laboratory research. Two such clinic visits were completed; one in Sierra Leone, Africa at the New Steps Clinic sponsored by Mercy Ships® and the second at the Bethany Crippled Children's Clinic in Kenya, Africa. During these visits, patients were fitted with prosthetic limbs manufactured according to our low cost design. These transfemoral prosthetic limbs can be manufactured using common handheld tools from readily available material. Prior to these visits, potential prosthetic component designs were developed and tested according to ISO Standards and compared against options available in developed countries. The focus of the author's research during involvement in this program was on the prosthetic foot component and comparing it and other prosthetic feet's biomechanical characteristics with those of an intact foot (Gonzalez, 2007; Vaughan, 2006).

SPECIFICATION SHEET

In developing the list of requirements for this project a Specification Sheet was generated. This table lists each requirement, target value, and verification test to determine whether the target value was reached at the completion of the project (Otto & Wood, 2000; Table 2).

Design of a Volume Adapting Lower Limb Pediatric Prosthetic Socket			
Specification	**Value**	**D/W**	**Test**
Manufacturing			
Manufactured using SLS	Y/N	D	Check
Compatible Material	Y/N	D	Nylon 11 or 12 manuf. For SLS
Maximum Build Size	W370 x D320 x H445 mm	D	Volume of Build Cylinder
Post Processing	Limited	D	Check
Biomedical/Biomechanical			
Return patient to typical ambulation levels	Y/N	D	Gait analysis
Distal Tibial contact	Y/N	D	User feedback
PTB design	Y/N	W	Check by prosthetist
Subject Age	3-10 years	W	Check
Adjustability			
Radial Volume Change	± 15 %	D	Measure final design
Longitudinal Volume Change	± 18 %	D	Measure final design
Accommodate Local and Uniform Change	Y/N	W	Analyze space in final design
Manual/mechanical Actuation	Y/N	D	Check
Durability			
Lifespan	3 years	D	Fatigue, wear, stress analysis
Water Absorption	TBD	W	
Wear	TBD	W	
UV Resistance	TBD	W	
Force to Actuate	TBD	W	
Static Load	45.7/2500 N	W	Static Load Test
Design Safety Factor	2	D	Check
Other User Requirements			
Interface With Other Components	Y/N	D	Compatible w/standard adapters
Slim Profile - Pant Leg Clearance	Y/N	W	User Survey
Cultural Applicability	Y/N	W	User Survey

Table 2: Specification Sheet

Manufacturing Requirements

Due to the complex contours of the residual limb and the need for customization of prosthetic sockets, Additive Manufacturing (AM) is particularly suited for this application. Additive manufacturing, specifically Selective Laser Sintering (SLS) has been previously applied to prosthetic socket manufacturing at The University of Texas at Austin (UT Austin). These sockets were designed to provide passive compliant regions for pressure relief in the socket wall (Faustini et al., 2005; Faustini, Neptune & Crawford, 2006; Faustini et al., 2006; Rogers et al., 2007). The volume adjustable prosthetic socket manufactured will, therefore, utilize this SLS technology. As this AM process utilizes thermal processes, thermoset plastics such as Nylon 11 or 12 (DuraForm PA® manufactured by 3D Systems, Rock Hill, SC) will be used. Metals, such as LaserForm™ A6 are available but lack the elasticity needed in a prosthetic socket design. Using the 3D Systems' Vanguard HiQ/HS SLS machine available at UT Austin, parts as large as W370 x D320 x H445 mm can be manufactured using this SLS machine (3D Systems, 2001). If an EOSINT P 730 machine were available, even larger parts in a build chamber of 700 mm x 380 mm x 580 mm would be possible (Electro, 2008). A final manufacturing requirement is that the additional post-processing work be minimized. Some additional post processing, such as bead blasting residual powder from part surfaces are required, however, additional steps of assembly and finishing should be limited.

Biomedical and Biomechanical Requirements

In designing a prosthetic socket that plays such an important role in the health and mobility of the user, certain biomedical and biomechanical requirements must be considered. To develop this list of requirements, Gordon Bosker, Certified Prosthetist and Orthotist at The University of Texas Health Science Center in San Antonio was consulted to determine some of the more pertinent requirements (2008). According to Bosker, the most important requirement is that the final socket must be capable of returning typical ambulation levels safely. Also, the prosthetic socket must have contact with the distal tibial end of the residual limb. This contact helps to ensure blood flow in the residuum that contributes to a reduction in the amputee's risk of developing verrucous hyperplasia (Dudek et al., 2006; Fergason, & Smith, 1999; Bosker, 2008). For additional patient comfort, the socket design should provide the patient with temperature control options if possible to help reduce temperature and moisture related sores (Perry, Ledoux & Klute, 2005; Lachenbruch, 2005).

This research focuses on the Patellar Tendon Bearing socket design, since it is the most frequently used design (Fergason & Smith, 1999). However, due to the design flexibility of the SLS process, any volume compensation techniques developed using the PTB style should be easily modifiable for any other lower limb prosthetic socket designs.

ADJUSTABILITY

As the intent of this socket is to compensate for volumetric changes in the residual limb of pediatric amputees, there are several requirements that pertain to the level, location, and method of adjustability of the prosthetic socket to be designed.

The target population for this research is children in developing countries between the ages of two to ten years. As such, growth must be accounted for in two primary forms: longitudinal and radial growth. The values used for this study were taken from the National Health Statistics' standard anthropometric data for adults and children in the United States, surveyed during 2003-2006 (McDowell et al., 2006). Though the target population is in developing countries, the use of this data provides a starting point for best-case average growth patterns for children. Adjustments from this data can be made on a case-by-case basis when specific patients are selected.

Radial changes are often the result of typical weight gain from maturation as well as possible fluctuations post amputation when muscle atrophy or edema can change the shape of the residual limb (Kurdibaylo, 1996; Golbranson et al., 1988). From the ages of four to eight, normal growth patterns can account for increases in calf girth measurements of as much as 4.6% per year for girls and 4.4% per year for boys (Meredith, 1950). From the ages of 2 to 10, an average increase of 3.65 kg/year for girls and 3.25 kg/year for boys is not uncommon (McDowell et al., 2006). Therefore a socket that can accommodate ± 15% total radial change will be the target for this design to accommodate normal growth over a three year period as well as higher normal body mass measurements in amputees and the potential for volume loss due to atrophy (Kurdibaylo, 1996).

Longitudinal changes in the specific location of amputation can help to provide the best measure for how much vertical adjustability is needed in the prosthetic introduced into that location. For this socket design therefore, the length change of the tibia is of greatest concern. The tibia can lengthen as much as 22.02 mm in a year for boys and 19.81 mm for girls between the ages of 10 and 17 (Smith, 2005). This corresponds to a target of 18% change allowance in longitudinal length of the prosthetic socket to be designed.

The particular type of volume change accommodation required determines the specific locations of the volume change. For radial change, it is hard to determine which of two ruling schools of thought prevails: local or uniform volumetric changes. In most cases, it seems the choice of method is made on a patient-specific basis (Bosker, 2008). In this study therefore, both uniformly and locally distributed volume changes will be accommodated. This will allow adjustability over the length of the residual limb with additional specific adjustment over sensitive regions identified by the prosthetist for the specific patient being fitted. Longitudinal changes should be accommodated such that the length of the socket itself is changed. Changing the length exterior to the socket, such as by shortening the pylon, is only a temporary fix. A socket with a fixed length means that the growing residual limb must continue to fit within a socket that is in contact with a smaller percentage of the limb than originally designed. In accommodating volumetric changes in this way, boney alignment changes from typical childhood maturation as well as weight fluctuations can be accommodated in the prosthetic socket design (Cummings & Kapp, 1992).

ACTUATION

One of the distinct differences between the socket to be designed and those previously completed at UT Austin and other AM sockets is the use of actuation in volume compensation. As the addition of actuation will extend the adjustability of the socket volume beyond passive compliance, this socket design will incorporate actuation mechanisms. The method of actuation used must meet certain requirements based on the needs of the customer. First, as the goal of this prosthetic socket is to make it applicable for use in developing countries, a manually powered actuation device is necessary due to the lack of readily available portable energy sources. Also, the actuation mechanism must be usable by the pediatric population. A survey of mechanisms regularly encountered by children provides a variety of analogies to be considered in the design of the actuation mechanism. These include mechanisms such as push buttons, switches, dials, latches or ratchets. Illustrations of such devices are provided in Chapter 4 Table 3. When considering designs intended to restrict child usage, mechanisms tend to incorporate multiple steps that are often in the opposite direction of the intended motion when the mechanism is released. Mechanisms specifically designed for children, therefore, tend to be large in size and require one-step actuation. In some cases, feedback for when the mechanism is successfully actuated is provided by means of sounds or exaggerated motion. The actuation mechanism designed for pediatric patients should, therefore, utilize these types of appropriate mechanisms.

Robustness

In designing a prosthetic socket for use in developing countries, special consideration must be made for ensuring the robustness of the design given the working environment of the device. The target lifespan for this device is a minimum of three years where typical devices last only one to two years for the target population of children from three to ten years of age. Literature has reported that children under five years of age typically require a new prosthesis annually, biannually between 5 to 12 years, and then once every 3 or 4 years over 12 years of age (Cummings, 2006). Increasing the lifespan of the socket has the potential to help lengthen the amount of time between fittings and therefore the monetary, material, and capital costs of fittings during the time where the greatest number of sockets is typically needed. Due to the fact that the user will most likely be using their prosthesis in a harsher environment than their developed country counterparts, the device must withstand prolonged exposure to water, sunlight and wear. An in-depth study of available materials for this prosthetic socket application is beyond the scope of this thesis for now. Therefore, for this study, the Arkema Nylon 11 material previously implemented will be used.

In addition, the device must endure extreme loading conditions so that the user is not injured in the event of an emergency. A survey of peak ground reaction forces (GRF) produced by elementary school children completing a variety of jumps found that the greatest GRF was attained while completing a maximal effort plyometric jump (a two footed vertical jump immediately preceded by a drop jump off of a raised platform). At minimum therefore, the socket, including any actuation mechanisms, should withstand a plyometric jump equal to five times the subject's body weight. (McKay et al., 2005)

Ultimately, the final prosthetic socket should be tested in accordance with the International Organization for Standardization standard 10328 for structural testing of lower-limb prostheses. This international standard accounts for both static and dynamic loading conditions (International, 2006). Other prosthetic socket designs manufactured by FDM have passed these rigorous testing standards, which suggests that a socket design manufactured using SLS that meets these standards should be achievable due to the greater material strengths available using SLS (Ng et al., 2002).

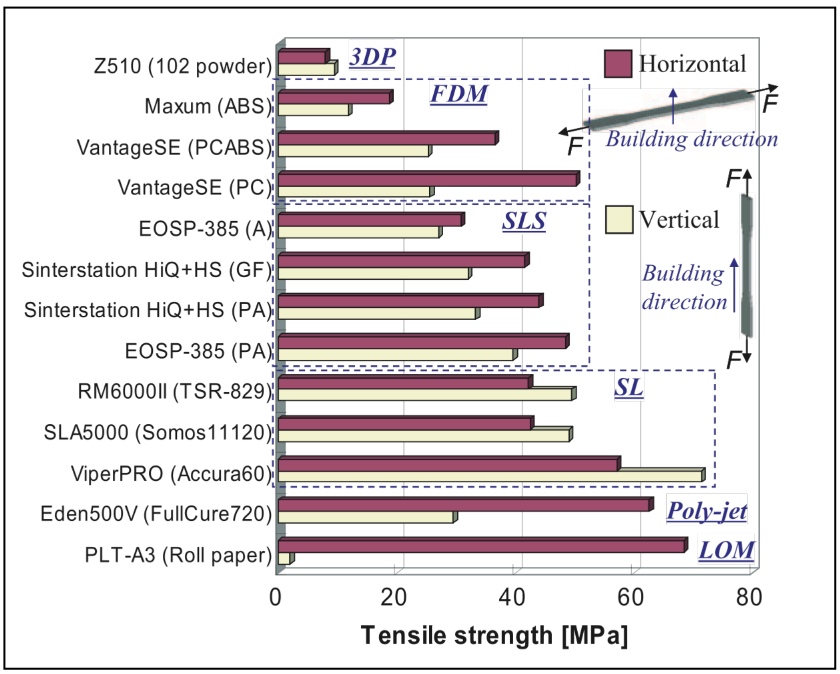

Figure 6: Comparison of Additive Manufacturing Processes to Tensile Strength (Kim & Oh, 2008)

As the focus of this thesis is limited to the design of volume compensation mechanisms rather than prototyping a final socket design, full ISO compliance testing is beyond the scope of the current research.

ADDITIONAL USER REQUIREMENTS

In addition to manufacturing, biomedical and biomechanical, adjustability, and durability requirements, there are several requirements pertaining to patient ease of use that must be addressed.

First, a simple interface with the remainder of the prosthetic must be achieved. This includes attachment to a suspension system as well as to a pylon adapter. There are several methods used for suspension of the prosthetic socket. The most popular include pin, belt, suction, and vacuum assisted suspension. Pin suspension is achieved when a pin fixed to the distal end of a tightly fitting liner is inserted into the socket and locked into the distal end of the socket. Another method of suspension is to use suction to grip the residual limb. This is often aided by the use of vacuum, known as a vacuum assisted suspension system (VASS), to maintain the proper suction level. The simplest method for suspension of the prosthetic limb is the use of a belt that fits around the socket and secures it to the upper portion of the residual limb or the waist. This suspension method therefore will be assumed for this research. (Bosker, 2008; Wirta, Golbranson, Mason & Calvo, 1990)

The connection with the components located distal to the socket is traditionally achieved using a pyramid style adapter (Figure 7).

Figure 7: Pyramid Style Adapter Components (Ossur, 2009)

The designed prosthetic socket, therefore, must mate with a universal adapter or have an integrated pylon adapter. Further reduction in the number of components could be achieved through the inclusion of the pylon and adapter into the socket design as long as the entire unit fits within the build volume.

A strong correlation between amputee body image, self-esteem, anxiety and depression has been demonstrated in the literature and motivates the design of prosthetic components that will help to improve body image (Breakey, 1997). This can be partially accomplished by designing components that are culturally appropriate for the patient. From personal experience and literature, it has been shown that the aesthetics and available functions of the prosthetic components can impact the acceptance of the amputee back into the community (Meanley, 1995). For example, in developed countries it is not unusual for an amputee to attempt to hide prosthetic components completely. In order for the amputee to accomplish this, the socket designed must remain inconspicuous under a pant leg or skirt without harming the garment. This means that sharp edges or joints must be removed or covered and a slim profile obtained.

Chapter 4: *Design Solution Concept Generation*

Concept Generation Methods

Concepts for this socket design were based on the aforementioned requirements and were generated using modified concept generation techniques such as Design by Analogy, Word Generation, and 6-3-5 (Otto & Wood, 2000). These techniques were used to generate concepts for the functions required of the socket design. Identification of these functions was accomplished throughout the process of establishing the requirements of the design solution during the initial customer needs analysis (Chapter 3). The socket functional requirements considered during the concept generation process were: accommodation of both radial and longitudinal volumetric changes in the residual limb, ability to interface with a socket suspension system and other prosthetic components, user safety and aesthetics, and methods to combine mechanisms designed for each function above. By focusing the concept generation process on each of these socket functions, a variety of detailed potential design solutions were generated using the design by analogy, word generation, and concept sketching techniques.

1. Design By Analogy

In Design by Analogy, design solutions for products that perform analogous functions are used to motivate generation of concepts for the current socket design problem (Otto & Wood, 2000). Analogies were drawn from existing prosthetic components, toys, tools, and other simple mechanical devices that are modified to create a change in volume. As the device to be designed is itself a prosthetic component, a review of other prosthetic components was completed to provide analogies upon which to draw. These include components such as suspension belts and pyramid pylon adapters (Figure 7).

Examples of analogies identified from commercially available toys were “Chinese Finger Traps” and Rollerblades (Table 3). The Rollerblade ratchet strap was of particular interest due to its incremental nature and ability to easily select a desired volume.

Commercially available tools also provided valuable analogies in the form of a pipe clamp and forceps. These tools are regularly used for applying pressure to an object to provide a secure hold but the applied pressure is variable and not permanent which is also desired in a socket design. Pipe Clamps in particular were considered due to their unique ability to expand or contract around a cylindrically shaped object (Figure 8).

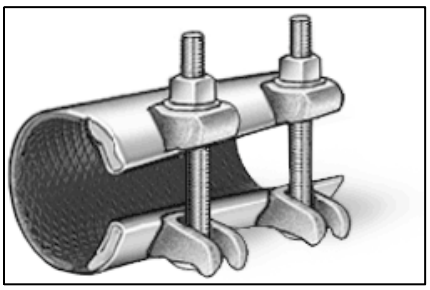

Figure 8: Pipe Clamp Example (www.McMaster.com)

Child Resistant	**Description**
	Sliding Door Cabinet Lock by Kidco, Inc. • Requires two motions to release: Slid along rail and unhook from handle.
	Door Knob Lock by Kidco, Inc. • Adds application of force to secure lock to doorknob before allowing rotation. • Spins freely when not engaged
	Adjustable Latch by Kidco, inc. • Requires pinching of release to unhook latch • Motion is in opposite direction of desired travel
	Child Resistant Pill Bottle Cap • Requires two motions to release: Push and Turn • Increased resistance also makes these harder for children to open. • Other designs require turning cap to align to marker and then flipping open.
Child Friendly	**Description**
	Hasbro Playskool's Sesame Street Busy Poppin' Pals • Incorporates multiple single action switches • Twist • Switch • Slide • Press • Large surface area, bright colors, and motion

Table 3: Analogies Considered for Actuation Mechanisms Pertaining to Children

	Rollerblade Buckle • Ratchet style mechanism • Lift buckle to release and slide to change size
	Childs Clothing • Buttons • Zippers • Velcro
	Walmart Razor A Kick Scooter • Foot break requires applied force on lever • Collapsing mechanism requires turning lever to release pin • Handles collapse by pulling out and folding
	Century Novelty Finger Trap • Push/Pull actuation • Minor diameter is a function of length

Table 3: Analogies Considered for Actuation Mechanisms Pertaining to Children (cont.)

Fasteners such as screws and push button releases, as seen on telescoping poles, were also inspirational for the design of connections between socket functions. Other mechanical devices identified as analogies to draw from were liner and torsion springs whose minor diameter changes as they are stretched or twisted. A final analogy identified was a camera aperture that provides an illustration of yet another method for changing the shape of a device to accommodate additional volume. From these existing technologies, analogies were drawn from the basic functions performed and applied to the design problem at hand.

2. Word Generation

An additional method used to generate possible solutions was through the generation of words to inspire design ideas. For this method, five participants, including the author, were given ten minutes to generate as many words as possible based on a seed phrase. All participants were mechanical engineering graduate students at The University of Texas at Austin spanning both biomechanical and design backgrounds. In order to encourage generation of unusual concepts, only two of the participants were informed prior to word generation how the final results would be used. Each participant generated at least twenty words for the seed phrase: Change Shape. Upon completion, participants were given a more thorough description of the socket design problem for which they would generate concepts in the next step of the concept generation process.

Concept Word Generation on Seed Phrase: *Change Shape*
Participant 1 – Inflating, Folding, Interlocking, Clinching, Cinching, Collapsing, Twisting, Rotate, Depress, Curl, Sag, Hinge, Spin, Unfurl, Wrap, Melt, Solidify, Bend, Aperture
Participant 2 – Bending, Folding, Telescoping, Expanding, Shrinking, Origami, Adjustable modules, Sliding, Reorganizing, Filling with air, Creating a vacuum, Linkages, Layering, Rotate, Elastic, Phase change, Transformers (robots), Umbrella, Bi-state materials/geometries, Springs, Freezing/Melting, Transport/Fluid Flow, Hinges, Stuffing, Crinkling, Flexibility, Nesting
Participant 3 – Bending, Break it, Stretch, Push on it, Fold, Snap together, Attach to something heavy, Apply pressure, Twist, Heat/Chill it, Pull Apart, Tear, Melt, Sand it, Pinch, Submerge, Fill, Remove air, Throw it against a wall, Transformers, Twirl, Twist, Ribbon, Crimp, Straighten, Brake, Solder, Glue, Drill, Cut, Burn, Centrifuge/Spin, Attach weights, Apply point force, Scratch, Hammer stuff into it, Chemical Stuff, Strings
Participant 4 – Stretch, Twist, Bend, Tear, Inflate, Charge, Press, Roll, Draw (as in metal working), Squeeze, Fold, Compress, Pump up, Fill, Form, Deflect, Melt/Freeze, Draw vacuum, Cut/Add material Expand Shim, Screw
Participant 5 – Expansion, Contraction, Add/Subtract material, Materials that stretch/contract, Fold, Unfold, Balloon, Shift, Bend, Insert additional material, Mold, Morph, Bending, Grow, Break/Chip away, Compress w/weight or pressure, Pulling, Stretching

Table 4: Concept Word Generation Results

3. Concept Sketching

Using the words generated from the method described above, a sketching based brainstorming process inspired by Otto and Wood's 6-3-5 method was completed. 6-3-5 is a graphical brainstorming technique used to generate a variety of design concepts using sketches rather than words for communication. For this activity, the same five participants used the words generated previously as the starting point for sketches of possible design solutions. The participants were not given a particular time frame to work in but asked to work for as long as they were continuing to generate concepts. After approximately thirty minutes of silent sketching, all sketches were collected and reviewed by the group.

GENERATED CONCEPTS

After the completion of the concept generation methods described above, the generated concepts were grouped according to the required socket function(s) they fulfilled. As a result, a variety of concepts for radial and longitudinal volumetric change, interfacing with a socket suspension system and other prosthetic components, user safety and aesthetics, and methods to combine mechanisms designed for each function above were obtained.

1. **Volume Adjustment**

Volume adjustment, as discussed previously (Chapter 2), consists of both radial and longitudinal volumetric changes. Of the volume compensation concepts generated, fourteen were for radial variation and seven were height change concepts. The more promising of these concepts are described in more detail here.

Radial Change

During generation of concepts to accommodate radial volume changes, words such as expand, inflate, stretch, twist, and insert were used to generate design solution concepts. Several of the more promising concepts are described here.

First in the radial change set of concepts is the camera aperture analogy concept. A camera aperture's function is to reduce the amount of light that passes through the lens. This is accomplished by sliding a series of overlapping sheets until the diameter of the circular opening reaches the desired size. This motion can be similarly used in the reduction of the approximately circular diameter of the prosthetic socket. To accomplish this, the primary socket walls would be sectioned into longitudinal plates that would slide around each other until the available volume was reduced by the desired amount. Figure 9 illustrates both the expanded and collapsed top views of the aperture radial volume compensation concept.

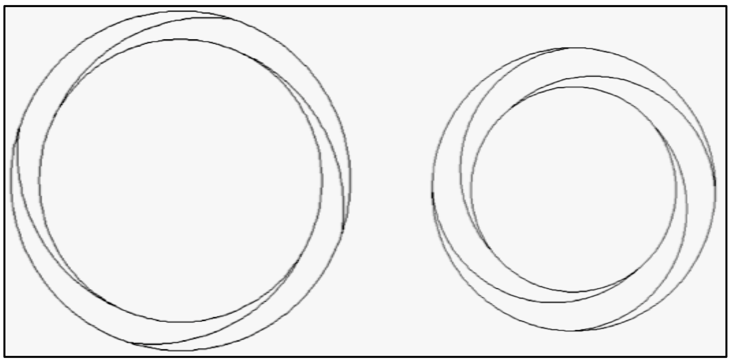

Figure 9: Aperture Design Concept (Top View)

Another radial volume compensation concept generated that relies on the motion of longitudinal plates is the Internal Sliding Plate concept. Unlike the Aperture concept, the Sliding Plate concept, illustrated in Figure 10, more closely maintains the internal socket shape while expanding without rotating with respect to the residuum. To accomplish this, sliders are built into the socket wall and allow for expansion of the socket along manufacturer selected vertical joints.

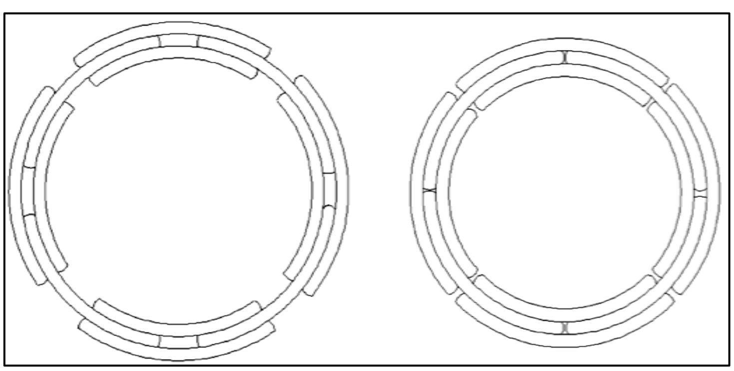

Figure 10: Internal Sliding Plates Design Concept (Top View)

Another analogy-based concept is the Pipe Clamp radial displacement method. This idea is based on a pipe clamp, as shown in Figure 8, whose available volume is changed by adjusting the size of the gap between the edges of the plate. Similarly, the socket wall can be modeled as a single plate that wraps around the residual limb. Contracting or expanding the space along a gap in the socket wall then achieves volume compensation. One possible gap design is shown in Figure 11.

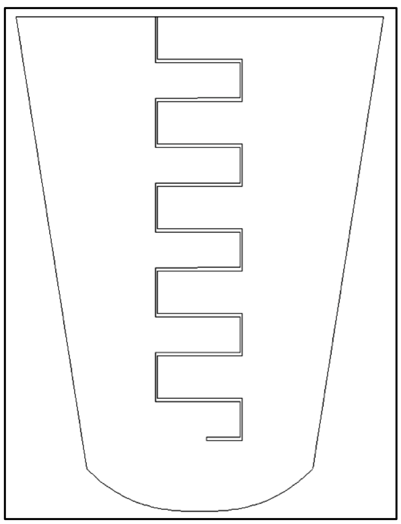

Figure 11: Possible Pipe Clap Design Concept

In the event that the gap made by the Pipe Clamp concept is greater than what is acceptable to the user, the Removable Wall Section concept is an alternative arrangement for the design of the gap. This concept helps to maintain stability and residual limb coverage by adding/removing sections of the socket wall in locations determined by the prosthetist during initial fittings. To help maintain the structure of the socket, joints, such as a sliding dovetail joint, can be used to align the removable wall section. The size of the sections can also be modified to account for a variety of radial size changes.

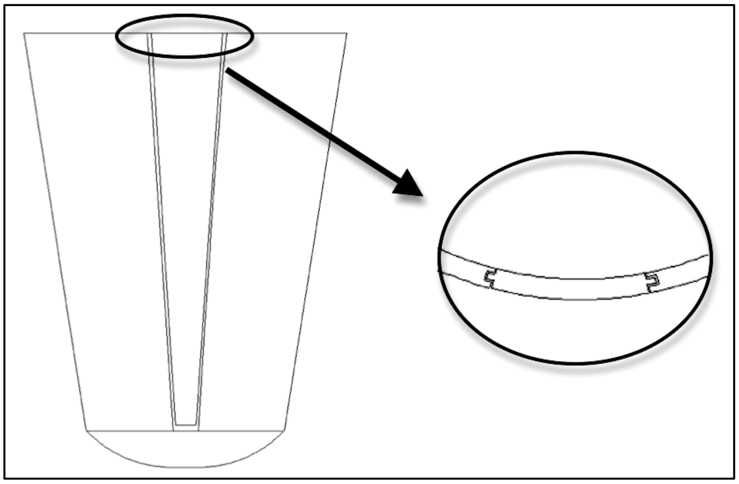

Figure 12: Removable Wall Design Concept

Similar to "slip" or "triple-wall" sockets, the Solid Socket Insert concept uses a single profile of the interior of the socket that is then scaled to a variety of sizes (Cummings & Kapp, 1992). These scaled internal contours are then used to manufacture socket inserts that can be added or removed as the volume of the residual limb changes. These inserts would be manufactured using the same method as an oversized base socket in which they fit. This base socket provides the primary structural support and interface with the remainder of the prosthetic limb.

In addition to those mentioned above, several other radial displacement concepts worthy of mention were generated. These include an analogy to an accordion where sections of the socket wall are crimped, allowing the wall to be stretched or contracted to accommodate socket diameter changes. Additional plate style socket concepts include the Hinged Sections and Pressure Plate concepts. In the Hinged Sections concept, the diameter of the socket is changed by rotating sections of the socket wall about the hinge point at the distal end of the socket (this concept is partially illustrated in the description of this fastener in Figure 19). The Pressure Plate concept consists of a variable number of separate surfaces that can be independently adjusted against the residuum to achieve the desired socket fit. These plates fit within a base socket and are actuated by mechanisms anchored to the wall of the base socket. As most of the plate style socket concepts require some sort of mechanism to maintain their deformed shape, the Spreader Socket concept addresses this issue. This concept incorporates a basic plate style socket concept with adjustable bands to maintain the desired shape of the socket. On these bands are angled protrusions that fit between the plates in the socket wall. As the band is moved along the length of the socket the protrusions force the socket to expand, causing the diameter of the socket to change. Inflation of chambers in the wall of the prosthetic socket could also be used as a volume compensation method. The final design concept to be discussed is the Linear or Torsion Spring concept. This concept is based on the diameter changes obtained by deforming springs by stretching or twisting. This is also very similar to the behavior of a Chinese Finger Trap.

Longitudinal Change

As with radial changes, concepts were generated using the methods described previously for accommodation of vertical growth. Of those generated, the leading concepts are described here.

The first longitudinal adjustment concept is the Plunger concept. This concept accommodates vertical growth inside the socket by actuating a distally located cap within the socket. This cap is designed to the contour of the distal end of the residual limb on one side and on the other to interface with an actuation mechanism such as the gearing system shown in Figure 13. To accommodate for the added space for both the growth and the actuation mechanism, an oversized external socket structure is required.

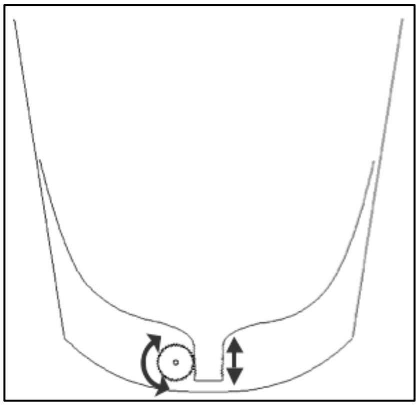

Figure 13: Plunger Longitudinal Height Adjustment Concept

Similar to the Removable Wall Sections concept that is used to accommodate radial change, the Interlocking Rings concept provides incremental changes in the length of the prosthetic socket. In this concept, additional length is added to the socket by way of rings that lock into one another as well as the socket. These rings can be added at any desired point along the length of the prosthetic socket. Figure 14 shows a possible arrangement of this concept applied at the proximal end of the prosthetic socket.

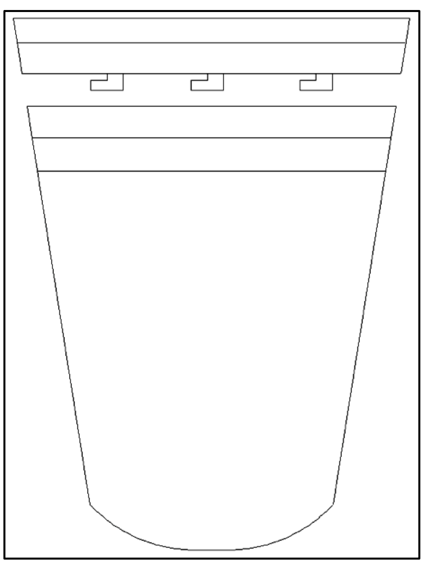

Figure 14: Interlocking Rings Design Concept

The Threaded Wall longitudinal adjustment concept uses threads to create a modular socket design. Figure 15 shows this concept being used to lengthen the socket on the distal end at the connection to the pylon, this concept can also be applied to a design similar to the interlocking rings concept. In this way each of the added rings connects to the socket by threading it onto the main socket.

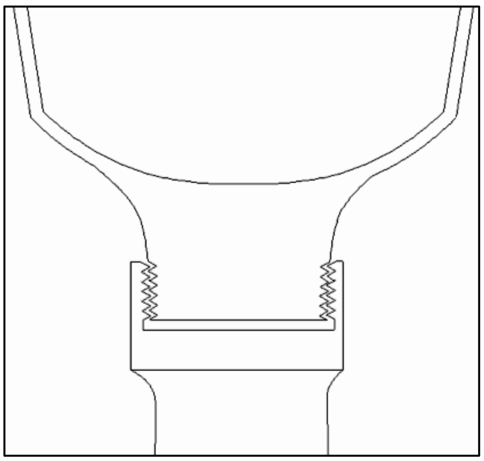

Figure 15: Threaded Wall Design Concept

As has also been previously done with pediatric prosthetic sockets (Cummings & Kapp, 1992), another method to accommodate vertical growth is the inclusion of solid inserts inside the distal end of the prosthetic socket. The remaining concepts generated for height adjustment pertain to the adjustment of the length of the pylon rather than the length of the socket itself. These include a Push Button style extender of the mounting of the pylon to the prosthetic socket. To change height in this concept the button is depressed until the interior section can be moved. The reshaped socket is secured by releasing the buttons back into the desired opening in the socket wall. This same method of adjustment can also be accomplished using a simpler design consisting of a separate pin to fit through the desired hole at the required height setting.

2. Pylon Attachment

In addition to volume compensation, the socket design must also incorporate an interface with the remainder of the prosthetic socket. This includes both interfacing with the suspension system as well as the pylon. As socket attachment can be achieved without significant modification of the prosthetic socket using commercially available methods such as suspension sleeves or belts, the focus of concept generation was therefore on the development of a pylon attachment mechanism.

A simplified method for attaching the pylon to the socket is achieved by rigidly securing the pylon to the socket. This is accomplished by manufacturing a rigid opening for the pylon to be inserted into and then secured using glue or set screws (Figure 16). This method relies greatly on the ability to align the prosthetic prior to manufacturing as adjustability is lost.

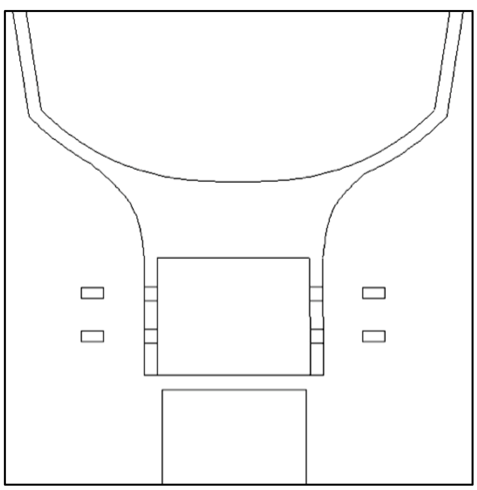

Figure 16: Set Screw with Through Holes Pylon Adjustment

Building on the work already completed at The University of Texas at Austin, the use of a reinforced SLS structure for connection of a pyramid adapter is a possible method for interfacing with the distally located prosthetic components to provide alignment capabilities. Illustrated in Figure 17 are existing embodiments of mounting plates for a pyramid adapter, such as the one illustrated in Figure 7. The mounting plate shown utilizes the manufacturing abilities of SLS to include specially designed slots to secure the nut in the socket mounting plate such that an additional tool is not needed.

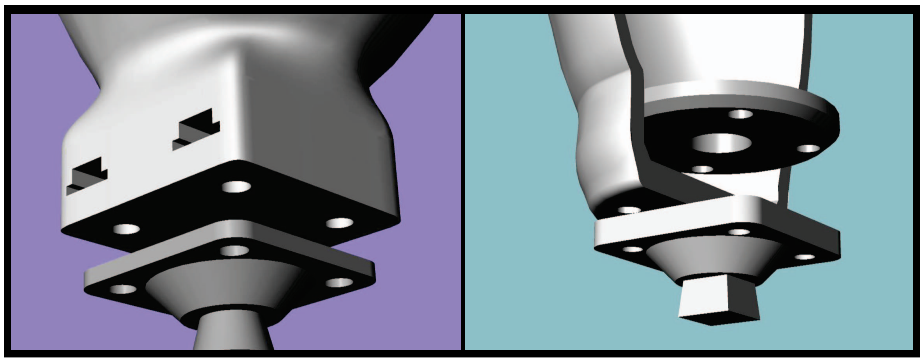

Figure 17: Existing Integrated Mounting Plate Designs (Rogers et al., 2007)

Building on this idea of an integrated mounting plate for a pylon adapter is the concept of incorporating the adapter into the socket itself. In this case, the pyramid adapter would be manufactured with SLS but perform the same alignment functions.

Further combination of components is accomplished by inclusion of not only the pyramid adapter but also the pylon. This produces what has been called a Monolimb design. The Jockey Club Rehabilitation Engineering Centre at The Hong Kong Polytechnic University developed one such design (Figure 18). Their monolimb is manufactured by molding polypropylene homopolymer.

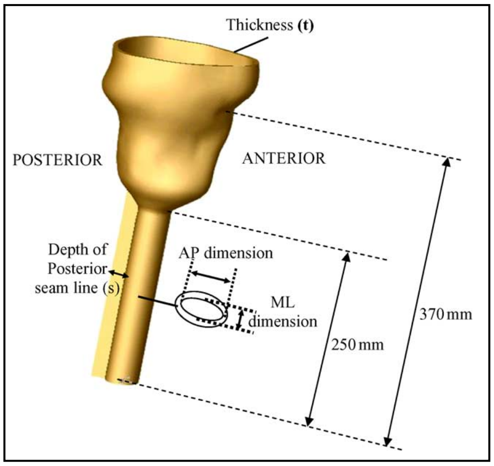

Figure 18: Monolimb Socket Design Example (Lee & Zang, 2005)

3. Fasteners

Eight methods to combine mechanisms designed for each function above were developed. Included in this set of concepts is the more promising fastener methods titled the Hinge, Ratchet, and Thread Fasteners concepts.

Used in the Hinged Sections radial change concept, the Hinge Fastener is one concept that can be used to connect different adjustment mechanism concepts. Figure 19 illustrates one possible embodiment of the Hinge Fastener, where separate plates rotate with respect to a common hinge point.

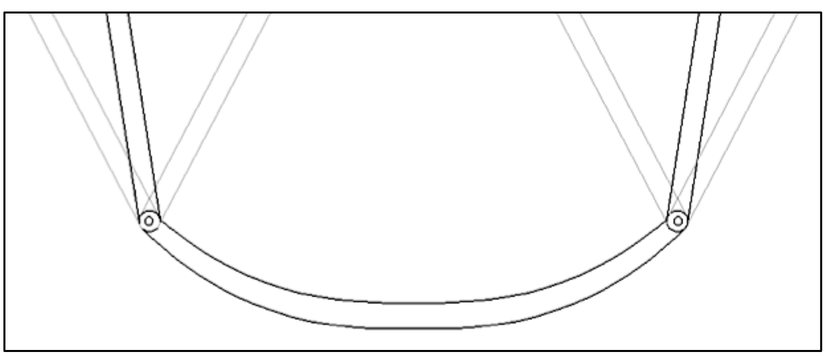

Figure 19: Hinge Fastener Design Concept

Joining portions of an adjustable socket design can be achieved due to the potential for SLS to manufacture functional Threaded Fasteners without additional machining steps. As previously shown, Threaded Fasteners can be used to adjust the longitudinal length of the prosthetic socket (Figure 15). In addition, the Screw Expander concept shown in Figure 20 demonstrates how a threaded fastener can be used to maintain the distance between socket sections.

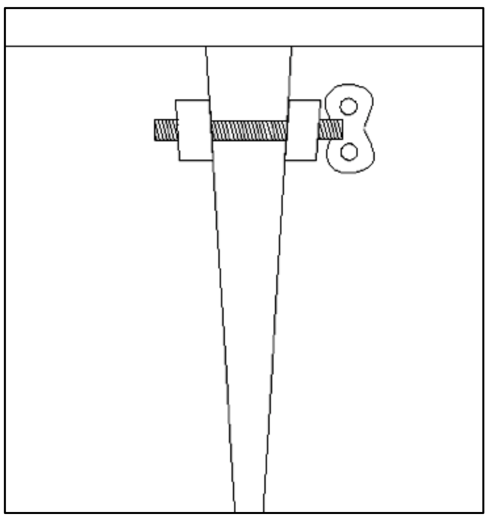

Figure 20: Screw Expander Design Concept

Akin to metal straps that maintain the shape of wooden wine barrels, the Horizontal Bands concept is another method for connecting sections of a modular style prosthetic socket (Figure 21). These straps can be permanently fixed at select vertical heights along the socket wall and then tightened radially into place using other connection methods such as the ratchet or threaded fastener concepts. Alternatively, the diameter of the bands can be fixed and then slid along the length of the socket to tighten or loosen around the changing residual limb shape. Incorporating guiding slots in the back of the band and corresponding rails on the socket pieces can further improve alignment of the modular sections.

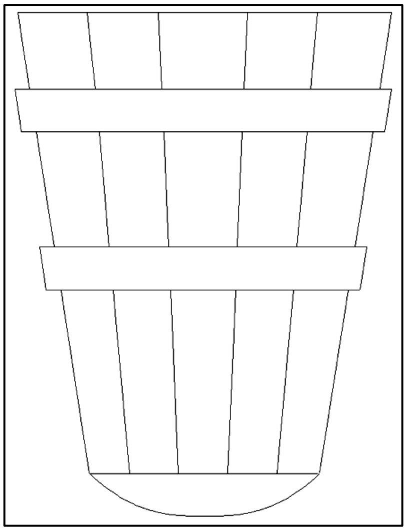

Figure 21: Horizontal Bands Design Concept

Analogous to rollerblade latches, the Ratchet Fastener concept uses angled threads to secure a joint in the socket design (Figure 22). Due to the nature of the concept, the amount of incremental change is set by the strength of the material and the design of the teeth. In general, increasing the number of teeth increases the adjustability of the connection. Adding additional interlocking teeth can help increase the joint strength. Removal of the Fastener can be aided by the addition of a release edge that allows the required force to be applied to disengage the latched teeth.

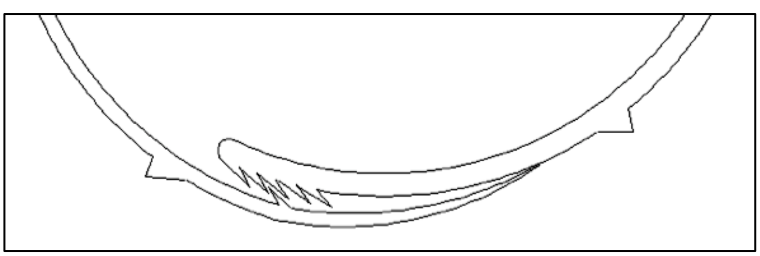

Figure 22: Ratchet Design Concept (Top View)

The final fastener concept generated is the Locking Fastener. As demonstrated in the Interlocking Rings longitudinal adjustment concept, the Locking Fastener is another

Fastener concept for the adjustable socket design (Figure 14). These locking pins are manufactured directly into the socket wall and utilize friction to secure the Fastener.

4. Safety

Though patient safety may not greatly impact the functionality of the final adjustable socket design, addressing patient safety during the concept generation phase is still important as it is a key patient need. Producing a prosthetic that accommodates volumetric changes but has a tendency to pinch or cause other types of harm is in direct opposition to the need for a comfortable socket that is driving this research.

As illustrated in Figure 22 above, one possible means of increasing user safety is by adding guards over the mating surfaces. This will help to protect clothing and skin from potentially being caught in the volume or radial adjustment mechanisms. This can also be accomplished by adding a liner or cover.

Since in most cases it seems the choice between local or uniform volumetric change methods is made on a patient-specific basis, both uniformly and locally distributed volume changes will be accommodated in this study (Bosker, 2008). This allows adjustability over the length of the residual limb with additional specific adjustment over sensitive regions identified by the prosthetist for the specific patient being fitted. Potential designs for these compliant regions will likely build on designs already generated at UT Austin. These include the spiral spring passively actuated compliant region (Figure 23.a) and the thin walled compliant region (Figure 23.b).

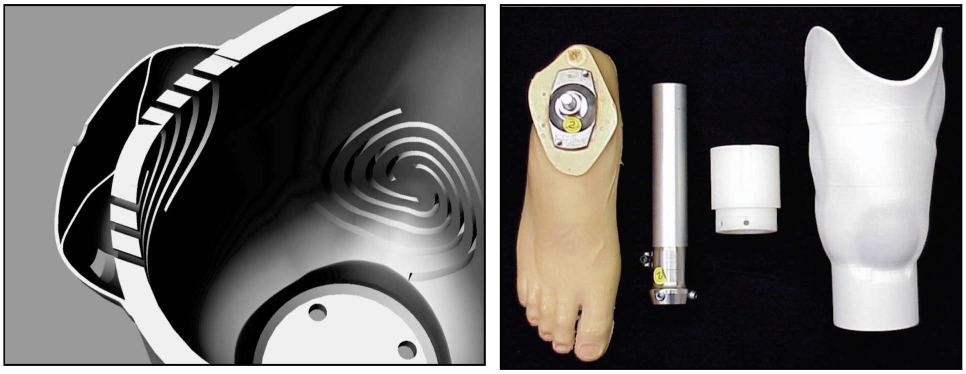

Figure 23: Existing Actuated (17.a) and Thin Walled (17.b) Compliant Region Designs (Rogers et al., 2007)

CONCLUSION

The variety of concepts presented in this chapter include a range of viable options for realizing the critical socket functions of accommodating radial and longitudinal volumetric change, interfacing with a socket suspension system and other prosthetic components, user safety and aesthetics, and methods to combine mechanisms. The most appropriate of these concepts must now be selected for final embodiment and validation. Chapter 5 therefore details the procedure undertaken to select the final concepts for further analysis.

Chapter 5: *Concept Selection*

Utilizing the concept generation methods described above, many design concepts were generated for each of the basic socket functions from which a final socket design could be assembled. However, these concepts must be narrowed down to the most promising concepts in each area in order to arrive at a final fully embodied volume adjustable socket design. In order to begin determining which final functional concepts would best meet the requirements identified during the initial customer needs analysis (Table 2), an elimination matrix was generated for each of the concept categories. These matrices provide a quantitative comparison of otherwise qualitative attributes by which the stronger concepts could be selected. Each matrix consists of rows of concepts whose performance is scored for each of the performance metrics in the subsequent columns by assigning a (-) 1, (+) 2, or (++) 3 point score. This three-point scale was selected as it provides more resolution than a binary scale while still maintaining a simple method for ranking the concepts. Each point is assigned a qualitative measure of performance for each criterion by which the concepts can then be ranked. These ordinal rankings are summarized in individual tables for each functional category (Table 5Table 11). The total score for each concept is summed across the metrics that are weighted based on their importance, the more important criteria being given twice the influence in the final score. These rankings and criteria used were based on the customer needs analysis and research and serve to provide a base from which to select a final concept in each functional area for further embodiment and validation. The rankings are not necessarily representative of empirical data but were intended to help remove bias in the selection process.

RADIAL CHANGE

Ten key criteria for selecting the most promising of the radial socket change concepts were determined based on the project requirements described in Chapter 3. Of interest in the design of these radial adjustment concepts is the ability of the socket to be strong, maintain proper alignment, and provide the resolution of volumetric change needed uniformly around the residual limb. In addition, the adjustment must maintain a PTB socket design while utilizing SFF. These criteria are summarized in Table 5 that also includes the ordinal ratings by which each concept was compared. Table 6 gives the final elimination matrix for the radial change concepts based on these ratings.

Criteria	Rating	Criteria	Rating
Strength	3 ++ No obvious stress concentrations	*Utilize SFF*	3 ++ Complex parts built as one
	2 + Possible stress concentrations		2 + Simple parts or mating surfaces
	1 - Apparent stress concentrations		1 - SFF not needed
Uniform Change	3 ++ Multiple small discontinuities	*Number of Parts* (Not including support structure)	3 ++ Single Part
	2 + Discontinuities		2 + Multiple Connected parts
	1 - Non uniform radial change with height		1 - Loose Parts
Maintains PTB Design	3 ++ Does not interfere	*Local Relief*	3 ++ Space for relief possible
	2 + Slight interference		2 + Limited space for relief available
	1 – Obvious interference		1 -- No relief
%Change	3 ++ Variable	*Slim Profile* (Not including support structure)	3 ++ Single wall thickness
	2 + Increments		2 + Double wall thickness
	1 - Limited/large increments		1 - >2 wall thicknesses
Wear / Fatigue	3 ++ Limited wear and fatigue	*Alignment*	3 ++ Does not change alignment
	2 + Cycling or rubbing		2 + Could change alignment
	1 - Cycling and Rubbing		1 - Changes alignment

Table 5: Radial Change Selection Criteria and Rating Scale

Criteria / Concept	Strength	Unif. Change	PTB	%Change	Wear Fatigue	Utilize SFF	#Parts	Local Relief	Slim Profile	Align.	**Total**
Accordion	-	-	++	-	-	+	++	++	+	-	31
Aperture/ Sliding Plates	+	++	+	++	-	++	+	+	+	++	38
Hinged Sections - Horizontal	-	-	+	++	+	++	+	+	++	+	36
Hinged Sections - Vertical	-	++	+	++	-	++	+	+	++	+	34
Inflation Concepts	-	-	++	++	+	++	+	++	-	-	36
Internal Sliding Plates	+	++	+	++	-	++	+	+	-	++	37
Pipe Clamp	++	+	++	++	+	+	++	++	++	-	46
Pressure Plates	+	++	+	++	+	++	+	+	-	+	36
Removable Wall	+	+	++	+	++	+	-	++	++	-	38
Solid Inserts - Scaled Inserts	++	+	++	-	++	-	-	-	+	++	37
Spring - Linear	-	-	-	++	-	++	+	-	-	++	30
Spring - Torsion	-	-	-	++	-	++	+	-	-	++	30
Spreader	+	-	+	++	-	+	+	+	++	+	36
Weight	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**1**	**1**	**1**	

Table 6: Radial Change Elimination Matrix

This elimination matrix demonstrates how the Pipe Clamp (both with or without inserts), Sliding Plates (both Aperture and Internal), and the Solid Insert concepts were among the strongest radial change concepts.

LONGITUDINAL CHANGE

As with the radial change concept elimination matrix, key criteria for selecting the most promising of the longitudinal socket change concepts were determined based on the project requirements described in Chapter 3. These criteria are similar to those for radial change but have been adjusted to reflect specific application to longitudinal change. The criteria are summarized in Table 7, which also includes the ordinal ratings by which each concept was compared. Table 8 gives the final elimination matrix for the longitudinal change concepts based on these ratings for the concepts.

Criteria	**Rating**	**Criteria**	**Rating**
Strength	3 ++ No obvious stress concentrations	*Utilize SFF*	3 ++ Complex parts built as one
	2 + Possible stress concentrations		2 + Simple parts or mating surfaces
	1 - Apparent stress concentrations		1 - SFF not needed
%Change	3 ++ Variable that can be made incremental	*Number of Parts*	3 ++ Single Part
	2 + Increments		2 + Multiple Connected parts
	1 - Limited/Large increments		1 - Loose Parts
Wear / Fatigue	3 ++ Limited wear and fatigue	*Slim Profile* (Not including support Structure)	3 ++ Single wall thickness
	2 + Cycling *or* rubbing		2 + Double wall thickness
	1 – Cycling *and* rubbing		1 - >2 wall thicknesses
Change Location	3 ++ Along length		
	2 + In socket		
	1 - Lengthen Pylon		

Table 7: Longitudinal Change Selection Criteria and Ranking Scale

Criteria / Concept	Strength	%Change	Wear / Fatigue	Change Location	Utilize SFF	Number of Parts	Slim Profile	**Total**
Interlocking Rings	-	+	+	++	++	-	-	18
Plunger	+	++	-	+	++	++	++	24
Solid Inserts - Height Spacers	++	+	++	+	-	-	++	20
Threaded Wall	++	++	-	++	++	++	+	25
Push Button Pylon Adjustment	-	+	+	-	+	+	+	18
Safety Pin w/through holes	++	+	+	-	-	-	++	20
Weight	**2**	**2**	**2**	**2**	**2**	**1**	**1**	

Table 8: Longitudinal Change Elimination Matrix

Based on this elimination matrix, the Plunger and Threaded Wall concepts were among the strongest longitudinal change concepts.

FASTENERS

The criteria used in the elimination matrix for the Fastener concepts were also selected based on the requirements of the project from Chapter 3. The strength of these mechanisms is of particular importance as their strength will largely determine the strength of a modular socket design. In contrast to this, the force to actuate these mechanisms must be reasonably expected from the target population that includes adolescents. Table 9 summarizes these criteria with their ordinal ratings. The completed elimination matrix is shown in Table 10.

Criteria	Rating	Criteria	Rating
Strength	3 ++ No obvious stress concentrations	*%Change*	3 ++ Continuous
	2 + Possible stress concentrations		2 + Increments
	1 - Apparent stress concentrations		1 - Limited/Large increments
Wear / Fatigue	3 ++ limited wear and fatigue	*Force to Actuate*	3 ++ Finger Tight
	2 + cycling or rubbing		2 + Significant Manual Force
	1 - rubbing and cycling		1 - Significant Force Requiring Tooling
Utilize SFF	3 ++ complex parts built as one	*Slim Profile* (Not including support structure)	3 ++ Single wall thickness
	2 + simple parts or mating surfaces		2 + Double wall thickness
	1 - SFF not needed		1 - >2 wall thicknesses

Table 9: Fastener Selection Criteria and Ranking Scale

Criteria / **Concept**	Height/ Radial	Strength	Wear / Fatigue	Utilize SFF	%Change	Force to Actuate	Slim Profile	**Total**
Hinge Fastener	Both	-	+	+	++	++	++	20
Horizontal Bands	Both	+	-	-	++	++	+	18
Locking Fastener	Both	+	+	++	-	++	-	19
Push Button Release	Both	-	+	++	-	+	+	16
Slider Fastener	Radial	-	+	+	++	++	+	19
Ratchet Fastener	Both	++	++	++	+	++	+	25
Threads	Both	++	+	+	++	+	+	21
Screw Expander	Both	++	+	+	++	+	-	20
Weight		**2**	**2**	**1**	**1**	**2**	**1**	

Table 10: Fastener Elimination Matrix

This elimination matrix demonstrates how the Ratchet, Threaded, and Hinge fasteners were the most promising fastener concepts.

INTERFACE WITH SOCKET COMPONENTS

Again, the criteria used in the elimination matrix for concepts interfacing with other socket components, particularly the pylon, were selected based on the requirements of the project from Chapter 3. These criteria are very similar to those required for the radial adjustment concepts as alignment and strength are important. As fine adjustments will be required here by a prosthetist to achieve proper socket alignment, the amount of change available is of particular importance. Table 11 summarizes these criteria and describes their ordinal ratings. The completed elimination matrix is show in Table 12.

Criteria	**Rating**	**Criteria**	**Rating**
Wear/Fatigue	3 ++ limited wear and fatigue	*%Change*	3 ++ Large Alignment
	2 + cycling or rubbing		2 + Limited Alignment
	1 - rubbing and cycling		1 - None w/out permanent adjustment
Ease of Use	3 ++ Universally known	*# Components*	3 ++ No Additional
	2 + Analogous		2 + Few Additional
	1 - New Technology		1 - Multiple Additional
Utilize SFF	3 ++ complex parts built as one		
	2 + simple parts or mating surfaces		
	1 - SFF not needed		

Table 11: Socket Interface Selection Criteria and Ranking Scale

Criteria / Concept	Wear/ Fatigue	Ease of Use	Utilize SFF	%Change	# Components	**TOTAL**
Threaded/Through Holes for universal adapter	++	++	+	++	-	20
Integrated Pyramid Adapter	-	++	++	++	+	20
Rigid Opening w/set screws	-	+	-	+	+	13
Monolimb design	+	-	+	-	++	15
Weight	**1**	**2**	**2**	**1**	**2**	

Table 12: Socket Interface Elimination Matrix

The Threaded/Through Holes for a universal adapter and the Integrated Pyramid adapter were therefore among the most promising of the pylon integration concepts.

Safety and Aesthetics

A specific elimination matrix for the safety concepts has not been generated, as many of the concepts are dependent on the final concepts selected for the radial, longitudinal, fastener, and interface concepts. Therefore, these concepts will be selected as needed based on the final design, incorporating the functional concepts selected.

Concepts Selected for Further Development

These elimination matrices were useful in narrowing the broad range of design concepts to a manageable few for further analysis. As shown, the preferred radial change concepts include the Pipe Clamp (both with or without inserts), Sliding Plates (both Aperture and Internal), and the Solid Insert concepts due to their potential to provide robust mechanisms for incremental radial change. Similarly, the Plunger and Threaded Wall longitudinal adjustment concepts were among the strongest. Connection of the prosthetic socket to other socket components was narrowed down to the Threaded/Through Holes for a universal adapter and the Integrated Pyramid adapter due to their ease of use and amount of available alignment. Incorporation of these concepts into a single socket design requires the use of fasteners. Of those generated, the Hinge, Ratchet, and Threaded fasteners were the most promising concepts.

These concepts therefore will be further pursued in design embodiment towards a final socket design. However, the possible full socket design relies on the ability of the compensation or integration methods to be fastened to each other. Therefore the design of the Threaded and Ratchet Fastener mechanisms will be the initial focus of analysis. This will help to determine which radial change, longitudinal change, and socket component integration methods will be the most plausible as their functionality and strength will likely rely on the design of these fasteners.

Chapter 6: *Design Embodiment and Verification Results*

This chapter presents the results of analyzing the performance of several promising subsystem concepts for the volume compensating prosthetic socket. These concepts were generated using methods such as brainstorming and design by analogy methods as described in Chapter 4. Four categories of subsystem design concepts were generated using this process, including designs for radial and longitudinal volumetric change, interfacing with a socket suspension system and other prosthetic components, user safety and aesthetics, and fasteners. The fasteners are the focus of the remainder of this thesis as they provide the means by which possible radial and longitudinal concepts can be incorporated into a final socket design. Among the fastener concepts generated, two promising fastening methods were identified: a hook style ratchet connection and a basic threaded fastener. These fastener concepts were common to several of the adaptable socket concepts. Development of these fasteners will enable the embodiment of a full transtibial SLS prosthetic socket that will provide both radial and longitudinal volume compensation for pediatric patients in developing countries. This chapter describes the design of test specimens of these concepts. The designs generated are analyzed here to ensure adequate strength and functionality and therefore feasibility of development of socket concepts that utilize these fasteners.

THREADED FASTENER DEVELOPMENT

Specimens were designed for verification of a theoretical threaded fastener model for use in a volume adjusting socket. The theoretical model of the threaded specimens is based on threaded fastener design principles for a power screw with square threads (Shigley, Mischke, & Budynas, 2004). The design and validation process followed for the development of a theoretical fastener model included the basic steps of:

- Initial specimen design based on theoretical models and preliminary builds to determine basic geometry.
- Initial specimen testing for geometric accuracy, load capacity, and model accuracy.
- Specimen redesign based on results of initial specimen tests.
- Redesigned specimen testing for geometric accuracy, load capacity, and model accuracy.

1. Threaded Fastener Theoretical Model

Illustrated in Figure 24, the threaded fastener specimens include an externally threaded bolt and corresponding internally threaded end cap. On the opposite ends of each threaded component is a tab to be secured inside the clamps of a tensile testing machine. As growth and dimensional accuracy is an issue with parts manufactured using SLS, a clearance c must be provided between mating surfaces to ensure that the specimens are functional. Due to the added clearance, the actual pitch p of the samples is not equivalent to twice the thread thickness t as is typically used in thread design. The pitch is instead equal to twice the thickness plus twice the clearance. The number of engaged threads n_t is initially set at seven as it has been experimentally shown that the seventh tread is the first thread that does not experience load (Shigley et al., 2004). The minor diameter d_r and t however are unknown and must be determined.

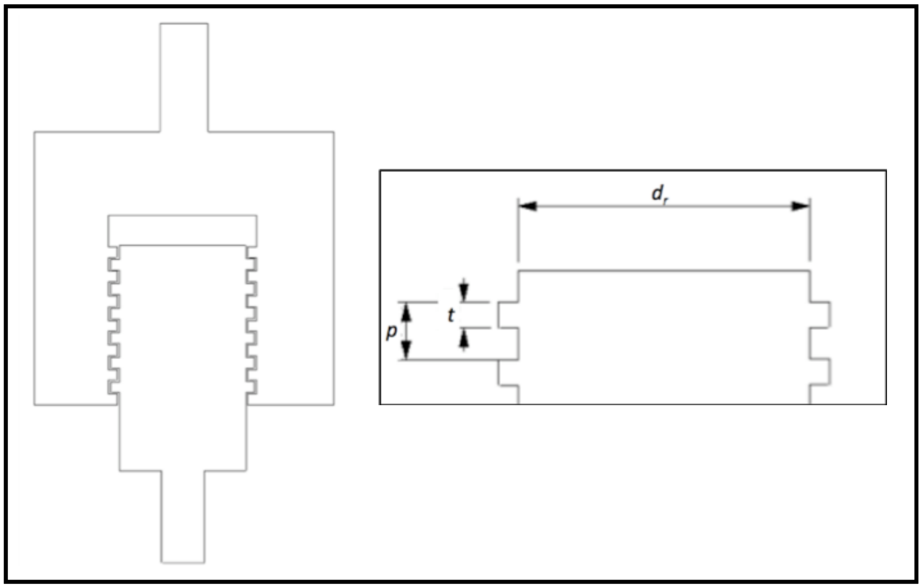

Figure 24: Basic Threaded Specimen Geometry

Initial values for d_r, and t to be used in testing were obtained using the relationship between these dimensions at failure, which occurs when the stress at the base of the threads exceeds the yield strength of the material. The bending stress at the base of the threads due to the moment caused by the applied axial force, F, in Newtons is (Shigley et al., 2004):

$$\sigma_b = \frac{Mc}{I} = \frac{6F}{\pi d_r n_t t} \tag{1}$$

By setting this stress equal to the yield strength of the material and solving for the minor diameter, the relationship between d_r and t at failure becomes:

$$d_r = \frac{6F}{\sigma_y \pi n_t t} \tag{2}$$

Using this relationship, and thread thicknesses greater than the previously identified minimum feature size of .5 mm, specimens were modeled using the solid modeling software Rhinoceros®. As the maximum applicable force of the available tensile testing machine is 5000 N, the modeled samples were designed to fail at 4000 N

(*3300 Series,* 2007). The geometries determined using this model are summarized in Table 13.

Set	Pitch (*p*)	Minor Diameter (d_r)	Thread Thickness (*t*)
A	2.2	15	0.6
B	2.5	12.5	0.75
C	2.8	10	0.9

Table 13: Threaded Fastener Specimen Dimensions (All units mm)

To verify the functionality of threaded specimens manufactured using these initial values and determine a minimum clearance, a series of preliminary builds was completed. One initial build included a full-scale model of these threaded fastener mechanisms designed for a potential application as the longitudinal height adjustment for pylon attachment. The final testing specimens were designed as scaled versions of this mechanism as the full-scale mechanism, according to the theoretical model, would not fail at loads available from the 3300 Series Instron® tensile testing machine used in this study. The larger size of the full-scale model ensures the specimen does not bend nor buckle during loading. In addition to a bending moment, it was determined that the full-scale mechanism must endure a 2500 N axial force. These scaled fastener testing specimens are designed to focus on the strength of thread designs under this axial loading condition. The magnitude of the anticipated axial force was derived from the maximum amount of force that could be exerted by a child while ambulating. This large magnitude is likely to occur while in a jumping or counter movement and can be as large as six times the user's body weight. For a 90th percentile 8 year old male, body weight is approximately 42 kg (92.3 lb) which is therefore a force of nearly 2500 N (McDowell et al., 2006).

A 3D Systems® Vanguard HiQ SLS machine was used to manufacture the threaded fastener test specimens. In the build setup, ASTM D638 tensile bars were also included for comparison to ensure that the resulting build is achieving published material properties for the material used. All part and build parameter settings were values used in previously successful builds completed during a Design of Experiments used to optimize these parameters, described in more detail in Montgomery (2009). Care was taken during arrangement of the parts in the build setup to ensure cylindrical parts were built vertically and portions of the build volume where known part curling issues occurred were avoided. The material used for this study was Rislan® D80 (Nylon 11) powder manufactured by Arkema. Equal parts virgin and overflow powder were used.

The preliminary builds resulted in appropriate geometry necessary for functional specimens and established in-build part orientation requirements. The builds also confirmed a clearance of .5 mm between mating surfaces was necessary. This information, as well as the same build setup, was utilized in the manufacture of two specimens from each set described in Table 13 for this preliminary study (Figure 25).

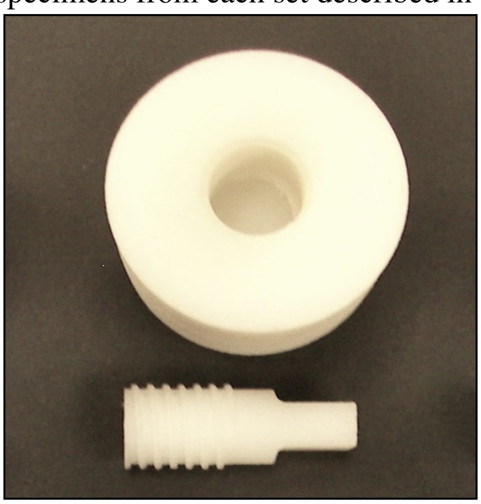

Figure 25: Final Threaded Specimen

2. Threaded Specimen Testing

Manufactured parts were tested for geometric accuracy, load capacity, and model accuracy. Geometric accuracy was determined by comparing the measured geometry of the sintered test specimens with the intended geometry as modeled. Load capacity and model accuracy were established through testing of manufactured parts based on a modified version of the ASTM D638. Fastener test specimens were pulled in tension to failure at a rate of 0.5 mm/min (Figure 26). For the test, an Instron® 3345 single column tensile machine with a load capacity of 5kN was used to obtain a load versus elongation curve for each sample.

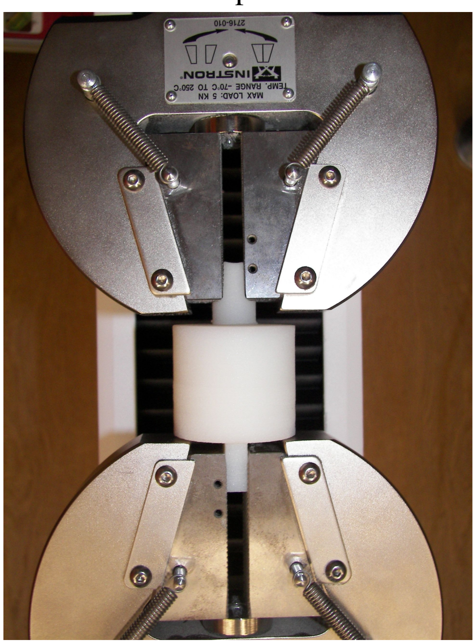

Figure 26: Threaded Specimen Testing Setup

The geometric accuracy of the threaded testing specimens was determined by measuring the primary dimensions, t, d_r, and p prior to loading and is summarized in Figure 27. This figure displays the average percent difference for all specimens for each of the varied dimensions. Error bars are included and show one standard deviation from the mean.

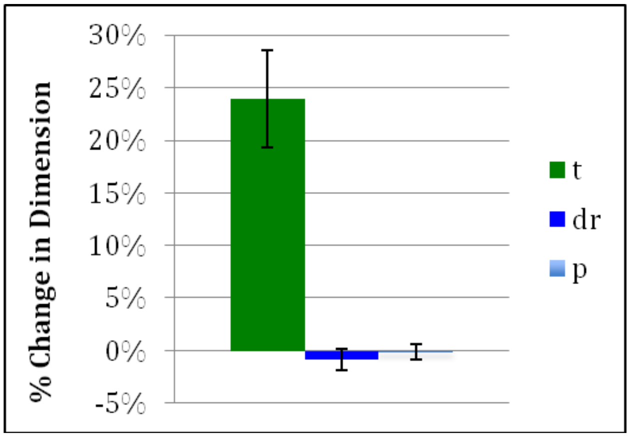

Figure 27: Geometric Accuracy of Threaded Fasteners

The nearly 24% increase in the thickness of the treads is the greatest discrepancy between the nominal dimensions and the measured values. This implies that there are higher levels of inaccuracy when attempting to build small features such as the threads on these specimens.

Each of the six threaded specimens was loaded to failure and load versus extension curves were obtained (see Figure 28). Each curve represents a single specimen and the point where the specimen yielded and broke are marked. Of the specimens tested, three of the specimens exceeded the intended failure point of 4000 N (bold horizontal line). However, only one of these three specimens actually failed in the threads. The remaining five yielded in the tabs by which the specimen was clamped in the testing apparatus. In addition, all of the specimens did not yield until more than 2500N. This is promising as an intended application for these fasteners will likely experience a load of 2500 N.

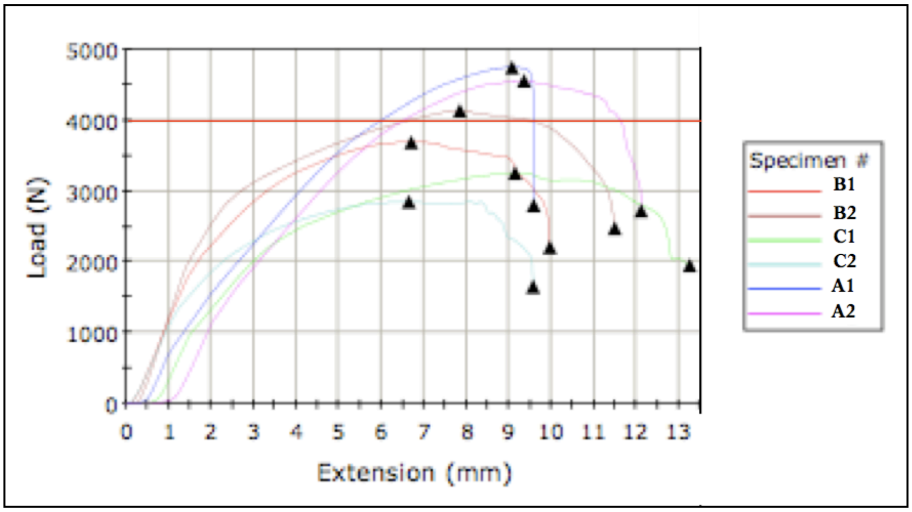

Figure 28: Load vs. Extension – Initial Threaded Specimens

As all specimens were designed to fail at 4000 N, the initial prediction of specimen failure based on the threaded fastener model described above was inaccurate. The model predicted that the specimens, labeled according to their corresponding dimension set A, B, or C described in Table 13, would fail at ~4000 N as the stress on the threads would exceed the yield strength of the material (Row 2 of Table 15). The yield strength of the material used was 48.3 MPa based on tensile test of the additional tensile test specimens included in the build (Table 14).

Direction	Tensile Strength	Standard Deviation	Modulus	Standard Deviation
X	49.12	0.45	1651.09	119.52
Y	47.49	0.95	1618.13	143.90
X and Y	48.30	1.11	1634.61	125.91

Table 14: Material Property Results - Test Build 1[1]

[1] These material property results differ from typical values published by *CES Edupack 2008*: Tensile strength of 55.2-65.5 MPa and Young's Modulus of 1240-1310 Mpa. This is likely the result of using higher than recommended build parameter settings, such as part bed temperature.

Only one specimen actually failed, but at 740 N above the anticipated limit. However, when the actual geometry of the specimens, which included the larger thread thicknesses, and the maximum load achieved were used in the model, the failure predictions were accurate and the only specimen predicted to fail did (Row 3 of Table 15).

	A1	A2	B1	B2	C1	C2
Max Load (N)	4740	4550	3690	4130	3260	2850
Expected σ (MPa)	60.63	60.63	58.21	58.21	60.63	60.63
Actual (MPa)	61.58	55.61	42.36	50.07	38.65	33.78
Failure?	Y	N	N	N	N	N
		Failure		Marginal		No Failure

Table 15: Threaded Model Results

Two specimens are considered 'Marginal' due to the fact that they did not fail even though the stress on the treads according to the model exceeded the measured yield strength of the material. However, these calculated stress values are close to the yield strength of the material and therefore it is uncertain whether they would have failed shortly in the threads if it were not for the failure in the tabs.

3. Final Threaded Fastener Design

A second iteration of the threaded specimens was completed in order to further verify the accuracy of the theoretical strength model of the threaded fastener specimens. Modifications to the experimental specimens focused primarily on ensuring failure occurred in the threads of the specimens rather than in the pull-tabs. In addition, adjustments were made for growth that occurred in the first round of experimentation.

The basic shape of the redesigned threaded fastener testing specimens remained unchanged from that used in the first round of experiments (Figure 24). However, as the specimens were failing at loads approaching the maximum allowable for the Instron tensile testing machine, the dimensions were modified to ensure that the specimens failed at 3000 N based on the theoretical model rather than 4000 N. This also theoretically helps ensure that failure occurs in the threads of the specimens rather than in the tabs. To accomplish this, the number of threads on the specimens was reduced from seven to four (Figure 29).

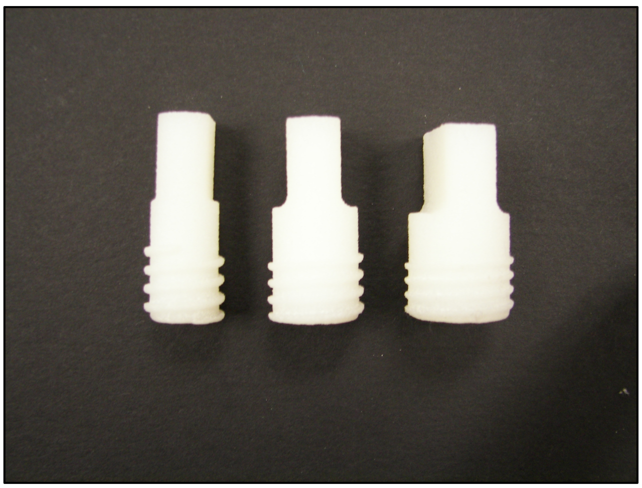

Figure 29: Redesigned Threaded Specimens

In addition, the geometry was modified to compensate for growth in the thickness of the threads. However, as the threads were already close to the minimum functional feature size manufacturable using our SLS machine, the amount of growth experienced in the first round of experiments is expected to occur on these parts. This amount of growth then is accounted for in the theoretical model described above. The final dimensions anticipated based on the theoretical model are listed in Figure 16. These samples were manufactured following the same procedures above.

Set	Pitch (p)	Minor Diameter (d_r)	Thread Thickness (t)
D	2.2	15	0.74
E	2.5	12.5	0.93
F	2.8	10	1.12

Table 16: Final Threaded Specimen Dimensions

4. Final Threaded Specimen Testing Results

The redesigned threaded specimens were again tested for geometric accuracy, load capacity, and model accuracy according to the methods used to determine the accuracy of the initial threaded specimen design. Five specimen pairs were manufactured for each of the three geometries desired and were used in testing.

Figure 30 displays the final change in dimensions of the sintered parts as compared to the anticipated dimensions. All three major dimensions experienced some growth; however, the greatest growth was again in the tooth thickness with a maximum percent difference of 10.75% and a mean of 4.75%. Error bars are included and show one standard deviation from the mean.

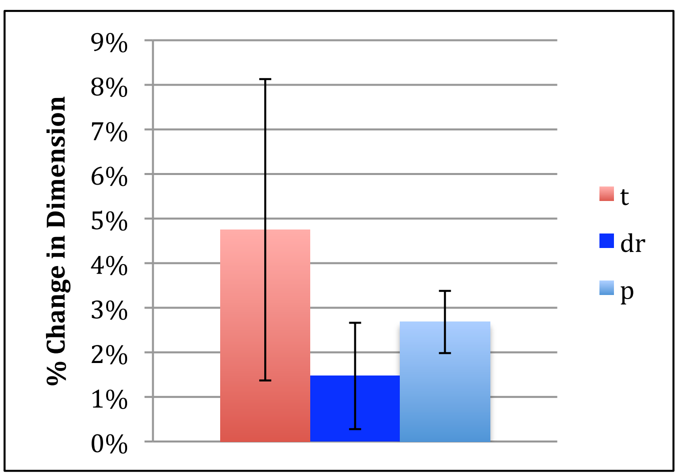

Figure 30: Geometric Accuracy of Redesigned Threaded Fasteners

In addition to determining the geometric accuracy of the manufactured specimens, load versus extension curves were obtained from tensile tests for each of the threaded fastener specimen pairs to determine their load capacity (Figure 31-Figure 33). Each of these figures summarizes the load vs. extension curve for each of the five specimens tested for each of the three geometries, D, E and F, described in Table 16. The maximum load values at yield were determined for each of the specimens and an average value for each sample set obtained. These average values, along with the average final specimen dimensions, were used in the verification of the theoretical model.

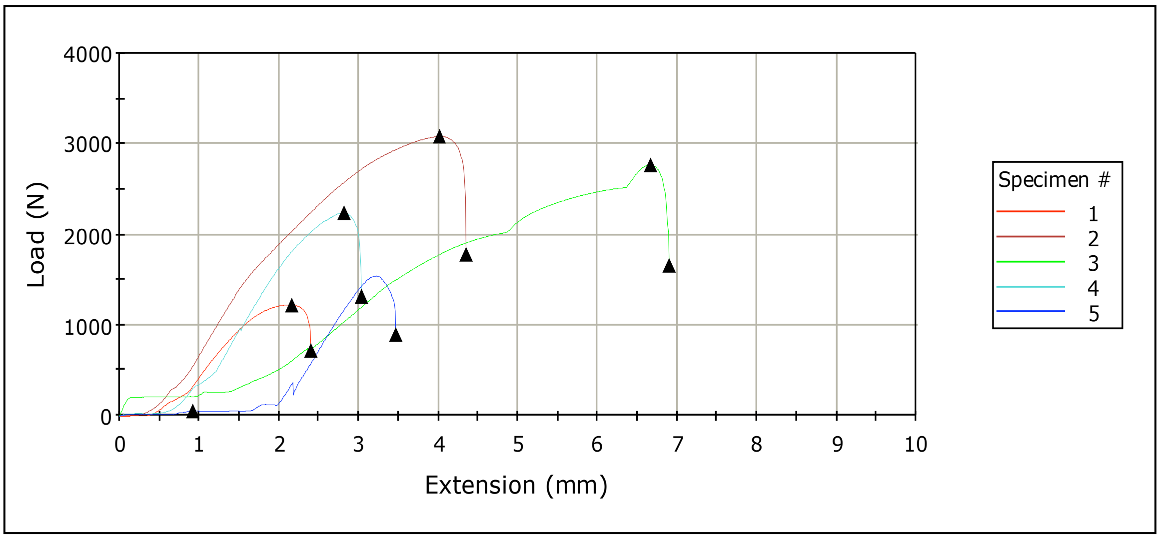

Figure 31: Threaded Fastener Load vs. Extension Curve - Sample Set D

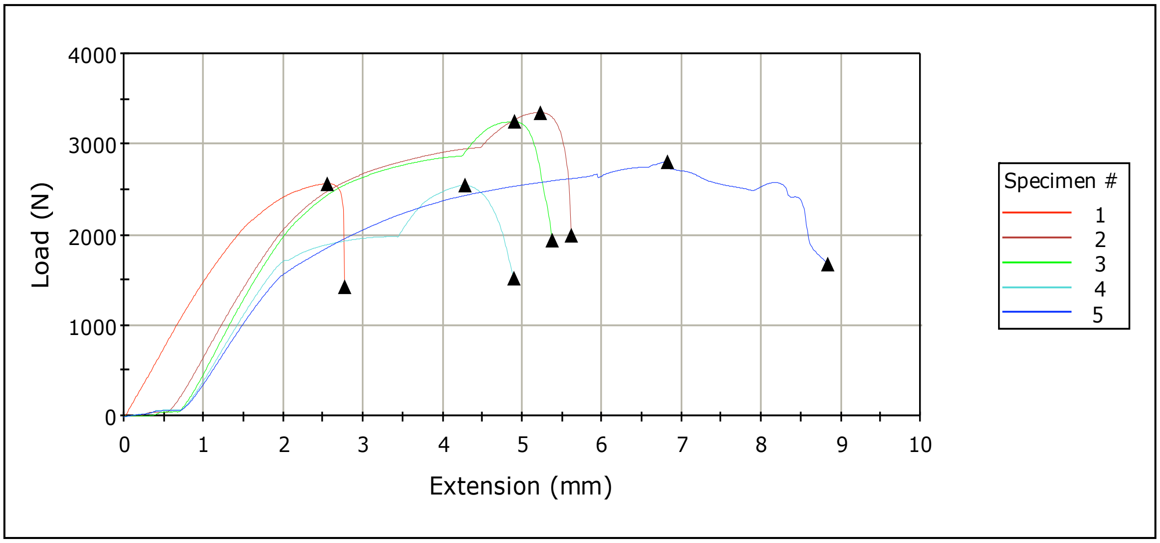

Figure 32: Threaded Fastener Load vs. Extension Curves - Sample Set E

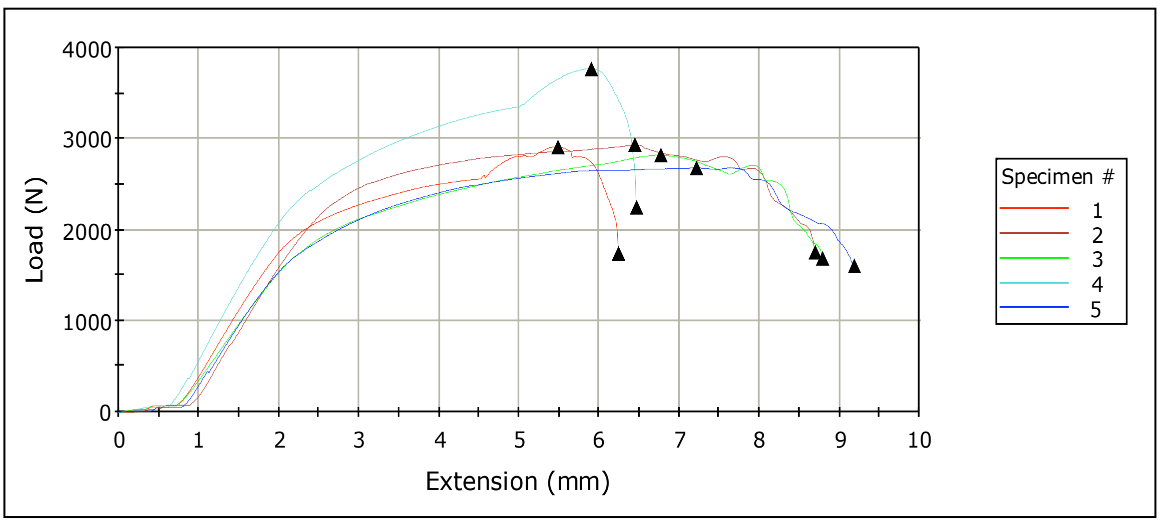

Figure 33: Threaded Fastener Load vs. Extension Curves - Sample Set F

Using the theoretical model developed above, values for the tooth thickness, pitch, and minor diameter were determined such that the specimens would fail at 3000N. This failure is defined as the point at which the threads on the specimens began to yield under the applied load or when the threads disengage. For the specimens designed using the above dimensions, the stress on the threads based on the theoretical model when loaded to 3000N is 64.81 MPa. This is greater than the yield strength of the material, which was 48.84 MPa (average of X and Y directions, Table 17). Thus the specimens are expected to fail by 3000 N.

Direction	Tensile Strength (MPa)	Standard Deviation	Modulus	Standard Deviation
X (top and bottom)	48.69	0.64	1670.82	225.66
Y (top and bottom)	48.99	0.96	1572.97	48.06
X and Y	48.84	0.81	1621.89	166.54
Z	33.08	5.76	1730.71	200.84

Table 17: Material Property Results - Test Build 2

The actual stress applied to the specimens based on the load at failure and the actual specimen geometry was also determined for the final specimens manufactured using the theoretical model. The stress on the threads, even compensating for actual loads and measured dimensions, remained above the yield strength of the material, the lowest being 49.01 MPa, within a standard deviation of the mean tensile strength measured for the build, 48.84 MPa. Therefore all specimen pairs were still predicted to fail based on the theoretical model. However, as shown in Table 18, only 60% of specimen pairs failed as predicted. Only 13.33% of the specimens tested, failed such that they were no longer functional. The resulting load and anticipated bending stress values on the threads used in determining whether the model and actual results agree are summarized in Table 18.

	D	E	F
Average Max Load (STDEV)	2,489.75 (612.31)	3,059.81 (599.28)	2,415.09 (796.75)
Expected σ (MPa)	64.81	64.81	64.81
Actual σ (MPa)	50.57	58.11	49.01
# of Failures in set	4 of 6	2 of 6	3 of 6
	Failure	Marginal	No Failure

Table 18: Redesigned Threaded Fastener Model Results

5. Threaded Fastener Conclusions

Though not all of the specimens failed at the expected load, these specimens have demonstrated how threaded fasteners under axial loading conditions can sustain loads greater than predicted by the theoretical model as well as the anticipated load of 2500 N. The implications of these results are summarized in more detail in Chapter 7.

RATCHET FASTENER DEVELOPMENT

Test specimens were also developed to determine an appropriate model of the ratchet fastener for use as a tool for designing an appropriate ratchet style fastener in a final socket design. The same basic steps were followed in the theoretical model development for the ratchet fasters as was implemented in development of the threaded fastener model.

1. Ratchet Fastener Theoretical Model

The basic geometry of the ratchet fastener is illustrated in Figure 34.

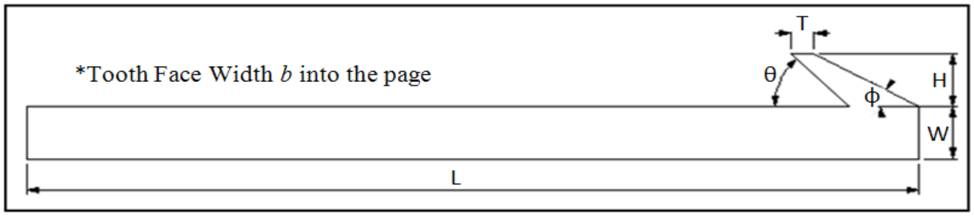

Figure 34: Basic Ratchet Specimen Geometry

Seven dimensions define this geometry that creates a two-part removable hook style fastener test specimen. These include the overall length L, width W, tooth face width b, tooth thickness T, internal tooth angle θ, external tooth angle ϕ, and the tooth height H. The length L was set such that the total length of the specimen when both halves are joined is 145 mm. A width W of 5 mm and tooth face width b of 38.1 mm were selected based on the potential inclusion of this fastener in a section of the wall (a potential application is described in more detail in Chapter 7). For all specimens, ϕ was five degrees less than the angle θ, such that the teeth will lock smoothly and provide clearance between successive teeth when used in a ratcheting application. The remaining dimensions were varied to determine their impact on the strength of the socket in order to determine a viable ratchet design.

The final specimen geometry for testing was determined using methods similar to those used to determine the threaded specimen geometry. As with the threaded specimens, a series of preliminary builds was completed to determine minimum feature size as well as to identify issues with growth (Figure 35).

Figure 35: Ratchet Sample Design Iteration (Bottom Final)

Several arrangements of the internal tooth angle θ and tooth thickness T were selected for testing of the ratchet fastener. For the initial test specimens, the angle and thickness were varied while the tooth height was determined by adjusting the tooth length to account for build growth and provide a fixed effective tooth length of 5 mm. The specimen dimensions used are summarized in Table 19. These parts were included in the same build as the initial threaded specimens and three specimen pairs for each set were manufactured for testing.

Set	Length, L (mm)	Height, H (mm)	Fillet, R (mm)	Angle, θ (deg)
A	77.9	3.4	1.25	35
B	77.31	3.09	1.25	30
C	76.9	2.6	1.25	25
D	76.62	2.62	1.5	25
E	77.59	2.33	1	25

Table 19: Ratchet Specimen Dimensions

In addition, since these specimens are intended for use in optimizing the strength of the fastener while minimizing its size, a Finite Element Model (FEM) was developed using COSMOSWorks® software to predict the strength of the proposed ratchet design. This FEM consisted of a solid model developed using SolidWorks® according to the desired dimensions of the ratchet specimen. As the specimens were clamped in the tensile testing machine, the samples were modeled to a length that did not include the end fixed in the clamps (Figure 36).

Figure 36: Ratchet Specimen Tensile Testing Setup

Therefore the model boundary conditions include fixed constraints at the end of the specimen where the clamp would have been as well as a pressure load, oriented parallel to the length of the specimen, distributed over the contacting surface area of the tooth. Figure 37 illustrates the basic constrained model used.

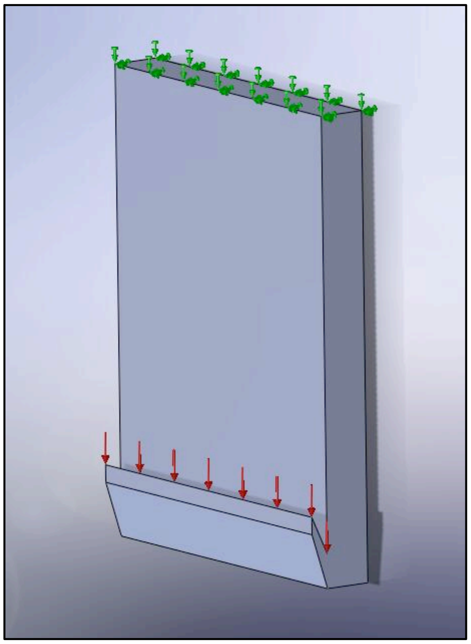

Figure 37: Constrained Ratchet FEM

The model was then meshed for a solid model static analysis using COSMOSWorks®. An iterative solution method for large displacements was used as the likely distance traveled by the tooth in testing was larger than the tooth thickness itself. A Convergence Plot generated by COSMOSWorks® was used to ascertain that the model was converging during the iterations. Figure 38 is an example of the convergence plots reviewed.

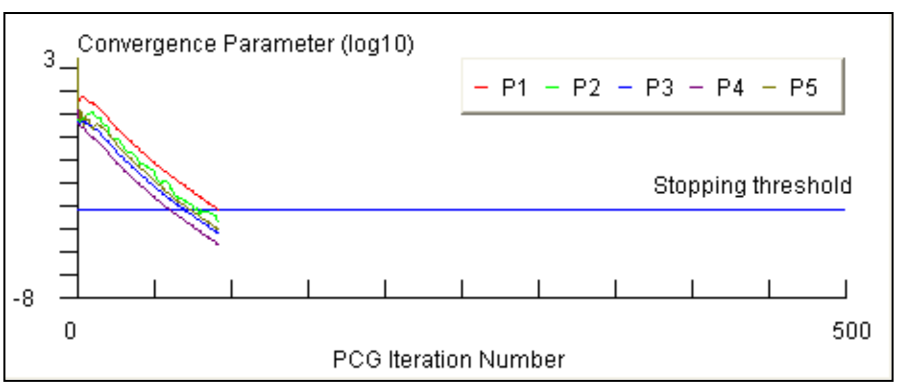

Figure 38: Example Convergence Plot

This FEM was used to obtain load vs. extension curve points for comparison with actual experimental testing results. This comparison helps to verify the accuracy of this model for use in designing ratchet style mechanisms for a final adaptive socket design.

One such load-extension curve point to be considered is at an anticipated load value. Analysis of the extension of the specimen at this load helps to determine whether the selected range of geometries is appropriate. This anticipated load was determined by approximating a socket as a thin walled cylindrical pressure vessel and solving for the hoop stress, and therefore tension, in a 38.1 mm (1.5 in) section of the socket wall. The assumption of using a thin walled pressure vessel was verified by ensuring that the ratio of the wall thickness to the diameter is small. For a wall thickness of 5 mm used in previously manufactured SLS sockets and a mean internal diameter of 98 mm determined from a scan of an adult male patient's residuum, this ratio is 0.05 and therefore the thin wall approximation will be used. The equation for the stress in a thin wall pressure vessel to be used is (Shigley et al., 2004):

$$\sigma = \mathrm{Pr}/t \tag{3}$$

where P is the pressure inside the socket, r is the radius approximation of a residual limb, and t is the wall thickness of the socket. Knowing that the tension in the section of the socket wall is equivalent to the stress σ over the cross-sectional area of interest, the final equation for the anticipated load in the socket wall is:

$$T = \frac{\mathrm{Pr}}{t}(t \cdot \Delta x) = \mathrm{Pr}\,\Delta x \tag{4}$$

Using the maximum stress level of 0.254 MPa recorded by Goh et al. for an adult male below-knee amputee and distributing it uniformly over the area of interest, Δx of 38.1 mm, this equation gives an anticipated maximum load of 47.5 N (2003). This load value is therefore used as a minimum strength value for the ratchet specimens to determine their applicability for inclusion in a final adaptable socket design. At this load, the stresses expected on the ratchet teeth for the initial specimens, as predicted by the theoretical model, are summarized in Table 20.

Angle (Deg)	Tooth Thickness (mm)	Extension (mm)	Stress (MPa)
35	1.25	0.33	2.98
30	1.25	0.28	2.70
25	1.25	0.25	2.86
25	1.5	0.26	2.75
25	1	0.23	1.89

Table 20:Anticipated Extension and Load on Ratchet Specimens Based on FEA

As these values are significantly less than the yield strength of the material, the initial values selected for *L, H, T,* and θ are further supported as valid initial choices for experimental testing.

2. **Ratchet Specimen Testing**

Testing of these ratchet specimens included determination of geometric accuracy, load capacity, and model accuracy. Geometric measurements and load versus elongation curves were obtained for the samples using the testing method described previously.

As with the threaded specimens, the manufactured ratchet test specimens were also measured for comparison with the intended values for the *H*, *T* and *L* dimensions. The percent difference between the expected and measured values for each of these dimensions across all specimens are averaged and displayed with error bars of one standard deviation in Figure 39. The greatest differences are found in the smaller part features, *H* and *T*. As both of these dimensions experienced shrinkage, indicated by the negative percent difference, these tooth features are too small at the point of the tooth and are therefore not building even though modeled. This was particularly noticeable in the sample set E where the tooth thickness *T* was the smallest, 1.00 mm. The length of the tooth for the specimens from set E were shorter due to the width of portions of the tooth point being less than the minimum feature size. This resulted in an average decrease in the overall height of the tooth by 52% for these specimens, while the other sample sets (A, B, C, and D) ranged from 16-32% difference in height.

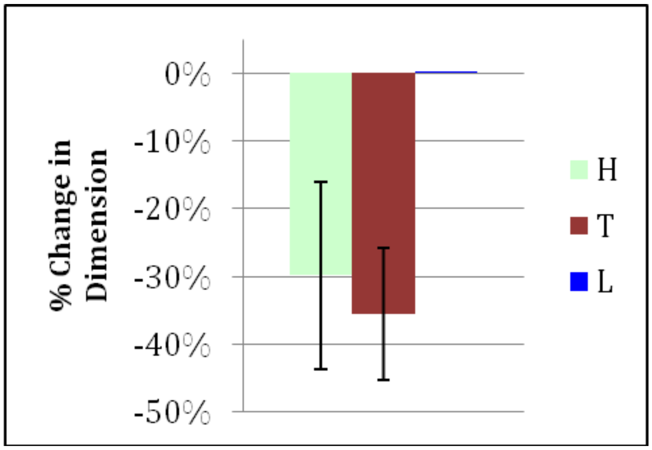

Figure 39: Geometric Accuracy of Ratchet Fasteners

In addition to measuring the geometric accuracy of the ratchet specimens, the load capacity of the specimens was determined using the testing method described above. Each of the 15 specimen pairs was tested to failure using the Instron® 3345 tensile testing machine and a load vs. extension curve was obtained (Example graph in Figure 40).

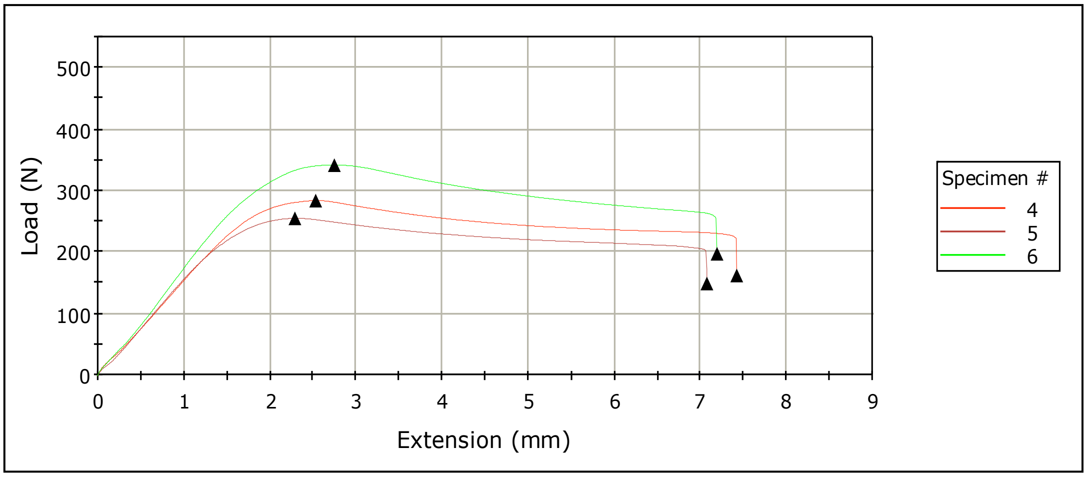

Figure 40: Sample Experimental Load vs. Extension Curve (30 Deg Internal Angle Ratchet Specimens)

The maximum load at yield, zero slope on the curve, was obtained and then plotted versus the intended angle θ and tooth thickness T (Figure 41). All samples failed at nearly six times the maximum load of 47.5 N anticipated for the intended application of these fasteners.

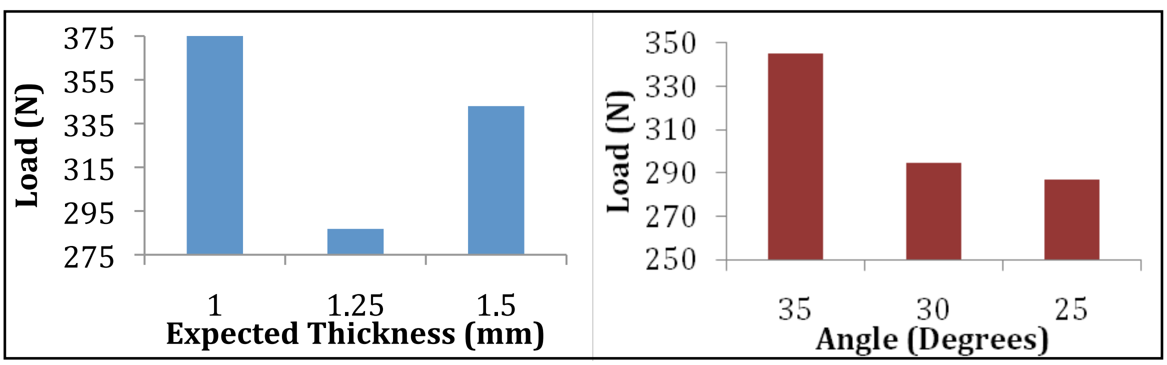

Figure 41: Load vs. Tooth Thickness (Left) and Angle (Right)

The accuracy of the FEA model described above was then determined by comparing the performance of the model at points along the load vs. extension curve for each specimen. Material properties used were the Nylon 11 material properties for tensile strength (48.3 MPa), modulus of elasticity (1635 MPa), and density (0.97 g/cm^3)

determined from tensile bars included in the build tested according to ASTM D638 (Table 14). The Poisson's ratio of 0.4145 used was the average ratio value available from CES EduPack Software produced by GRANTA (*PA*, 2008). Average actual specimen dimensions obtained from measurement of specimens while ascertaining the geometric accuracy were used in verifying this model. Using the FEM, load – extension pairs were obtained at four different load values, one at yield, three others equally spaced along the linear elastic range of the curve, and one at the anticipated load of 45.7 N. These were then compared with the corresponding average load – extension pair on the experimental curve (Figure 42 & Figure 43). The actual experimental load – extension curve points used for comparison with the model were the average extension achieved by the three tested specimen pairs at the desired load.

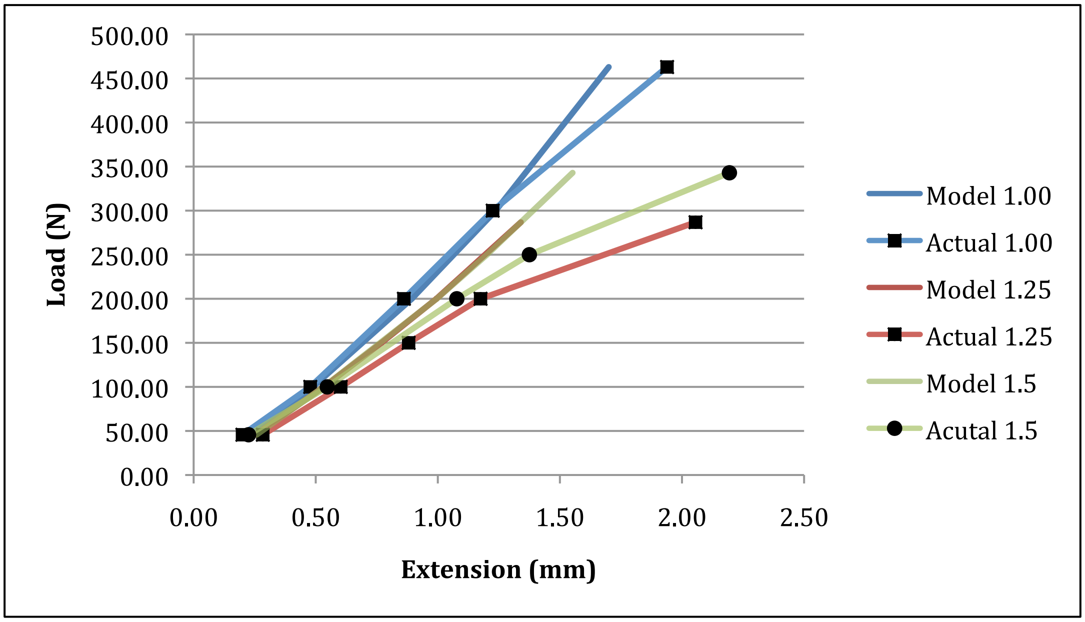

Figure 42: Comparison of Ratchet Theoretical Strength Model to Experimental Data - Range of Tooth Thicknesses (1, 1.25, and 1.5 mm)

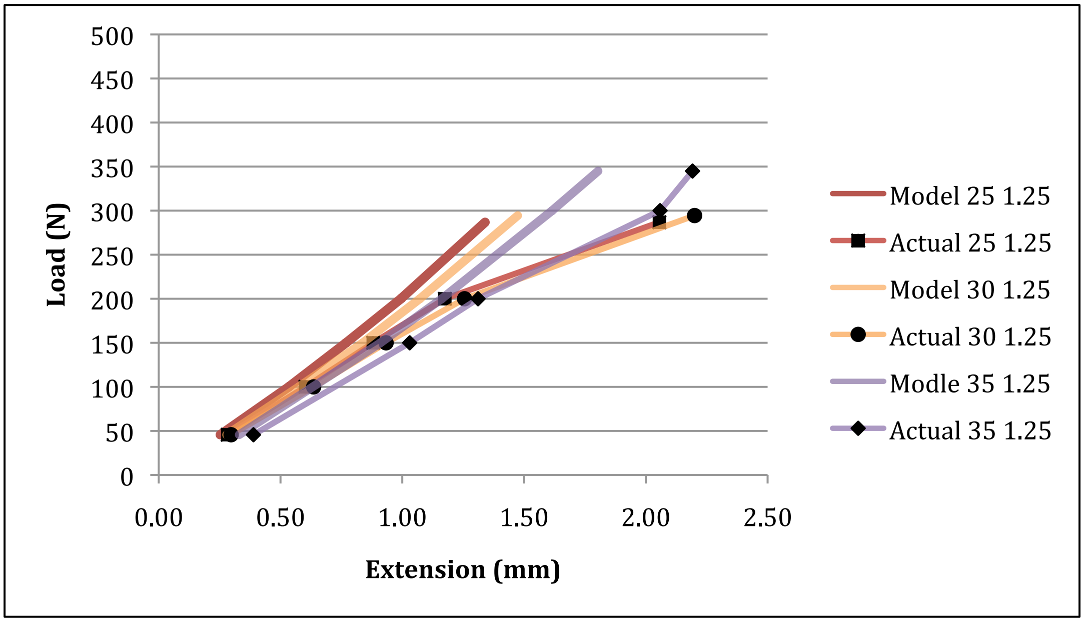

Figure 43: Comparison of Ratchet Theoretical Strength Model to Experimental Data - Range of Ratchet Internal Tooth Angles (25, 30, and 35 Degrees)

In order to quantify the amount of deviation of the theoretical model from the experimental data, a relative difference ratio was used. This ratio is defined by:

$$RD = abs\left(\frac{x_{actual} - x_{predicted}}{\max(x_{actual})}\right) \times 100\% \tag{5}$$

where the difference between the extension value calculated by the model, $x_{predicted}$, for a given load is subtracted from the measured value at the same load. This difference is normalized to the maximum measured extension for the particular specimen. This normalization enables comparison of results across samples as well as along the load vs. extension curve. Normalization is necessary as the magnitudes of the extension value differences are different across specimen designs as well as along the curve. Figure 44 shows the increasing trend of the relative difference percentages with respect to applied load with the load at yield circled.

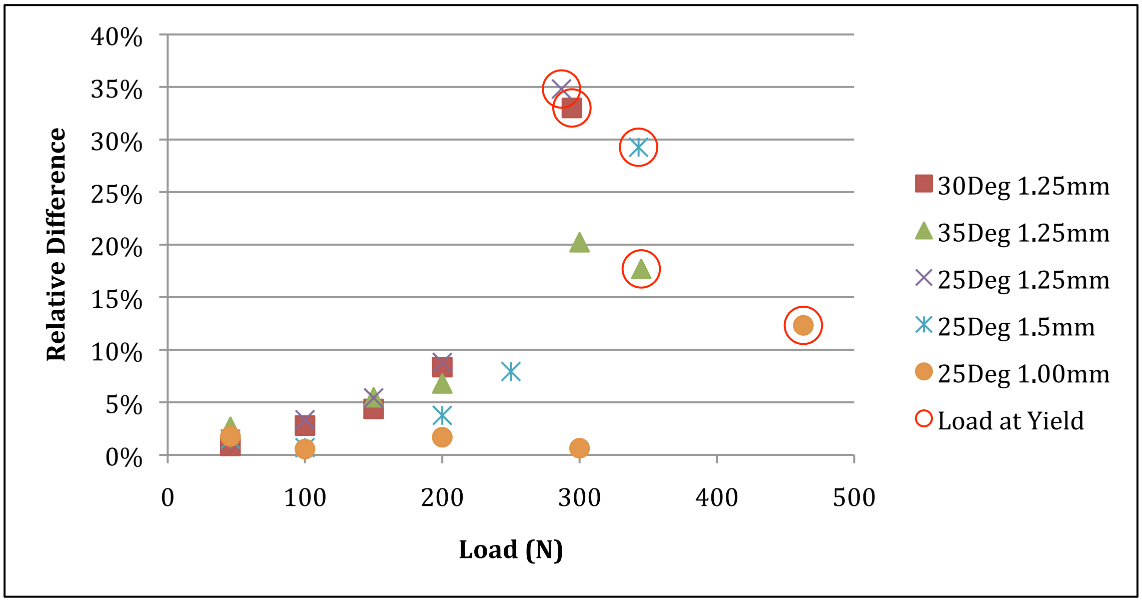

Figure 44: Relative Percent Difference of Ratchet FEM Results from Experimental Data vs. Load (Load at yield circled)

As shown in these graphs, the deviation of the model from the experimental data is greatest as the load on the ratchet tooth approaches the yield strength of the material. At this load the model deviates 13-35% from the experimental data. In the linear portion of the curve however, the difference between the theoretical and experimental data is less than 10%.

3. Final Ratchet Fastener Design

Based on the results of the initial ratchet testing, further improvements were needed to address growth/shrinkage issues, to investigate strengthening the specimens, and to determine the impact of changing the direction of loading on the ratchet tooth. The general shape of the ratchet specimen was maintained from the previous specimens, however one major adjustment was made in an attempt to strengthen the specimens and ensure full part manufacture. Instead of having the ratchet tooth come to a point as in the previous design, a fillet with radius R was added to the tip of the ratchet tooth as well as along the crease (Figure 45).

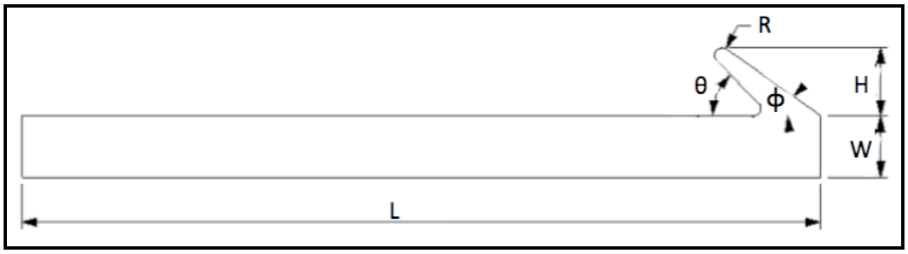

Figure 45: Redesigned Ratchet Specimen Geometry

This area along the crease in the previous design was already empty as the thickness of the other tooth, when fitted together, prevented a tight fit. Matching the radius of the fillet in the crease with that on the tooth edge was theorized to help the specimens mate completely and direct more of the load into the stronger area at the base of the tooth. Use of a minimum fillet radius equal to the minimum feature size previously discussed (0.5 mm) helps ensure that all features are larger than the minimum feature size and will therefore sinter properly.

A range of values for the internal tooth angle θ and tooth fillet radius R were selected for testing the redesigned ratchet fastener using methods similar to those described previously (Table 21).

Set	Length, L (mm)	Height, H (mm)	Fillet, R (mm)	Angle, θ (deg)
F	80.65	4.82	.5	35
G	74.8	4.41	.5	30
H	73.28	4.07	.5	25
I	71.87	4.52	.75	25
J	76.02	3.15	.25	25

Table 21: Redesigned Ratchet Dimensions

Initial verification of the specimen geometry using the FEM described previously showed that the stress on the tooth at the anticipated load of 47.5 N had a safety factor greater than the minimum desired (Table 22).

Angle (Deg)	Fillet Radius (mm)	Extension (mm)	Stress (MPa)
35	0.5	0.43	2.61
30	0.5	0.32	3.15
25	0.5	0.22	1.99
25	0.75	0.28	2.61
25	0.25	0.30	2.79

Table 22: Anticipated Extension and Stress on Redesigned Ratchet Specimen Based on FEA

As the current testing specimen for the ratchet fastener only accounts for one direction of applied force, an additional specimen for determining the amount of force required to make the specimens slip in another loading condition also provides useful information. This testing specimen was designed using the same ratchet tooth geometry as the redesigned ratchet but the length of the specimen was reoriented 90° from the original direction of pull (Figure 46).

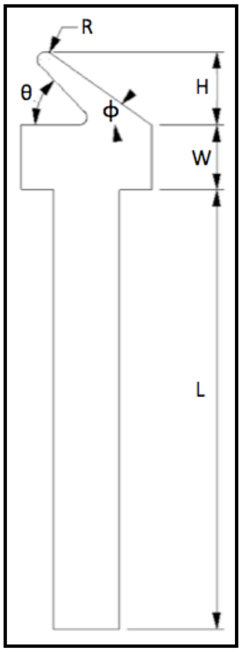

Figure 46: Rotated Redesigned Ratchet Specimen Geometry

A range of values for tooth angle θ and tooth fillet radius R similar to those used in the redesigned ratchet sample described above was selected and deviates only in the length L. These values and the corresponding lengths and tooth heights are summarized in Table 23.

Set	Length, L (mm)	Height, H (mm)	Fillet, R (mm)	Angle, θ (deg)
F	80.65	4.73	.5	35
G	74.8	4.41	.5	30
H	73.28	4.07	.5	25
I	71.87	4.52	.75	25
J	76.02	3.15	.25	25

Table 23: Rotated Redesigned Ratchet Specimen

Four specimen pairs were manufactured for each of the five geometries desired in both orientations for a total of 40 ratchet specimen pairs. These specimens were built in the 3D Systems® Vanguard HiQ SLS machine using the Nylon 11 material and machine and material parameter settings previously determined.

4. Final Testing Results

The redesigned and rotated ratchet specimens were also tested following the procedures previously described for testing ratchet specimens, the geometric accuracy, load capacity, and model accuracy. To determine their geometric accuracy, the redesigned and rotated ratchet specimens were measured for comparison with the intended values for the *H*, *T* and *L* dimensions (Table 21 & Table 23). The percent difference between the expected and measured values for each of these dimensions across all specimens are averaged and displayed with error bars of one standard deviation in Figure 47. Again, the greatest differences are found in the smaller part features, *H* and *T*. The average values for each of the major dimensions obtained from these measurements were used in the final FEA discussed later.

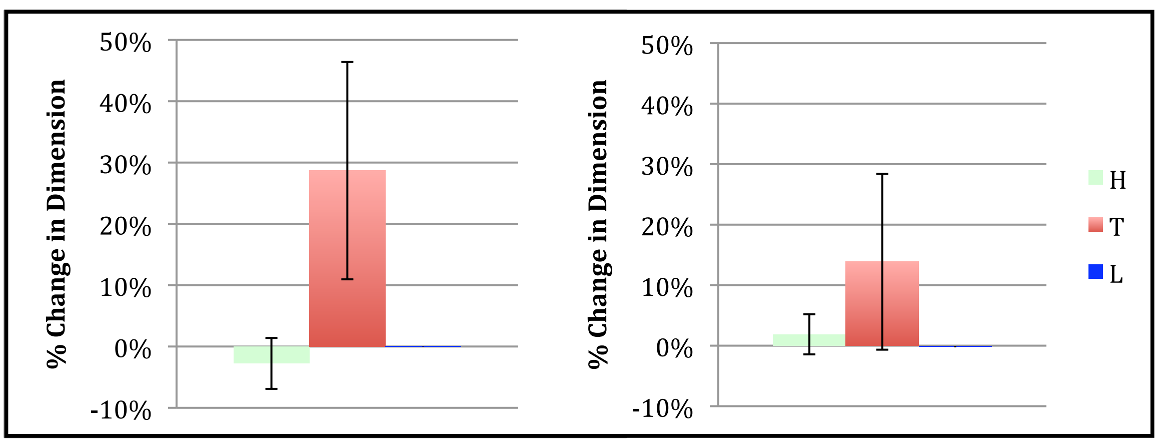

Figure 47: Geometric Accuracy - Redesign (Left) and Rotated Redesign (Right)

In addition to measuring the geometric accuracy of the redesigned ratchet specimens, the load capacity of the specimens was determined using the testing method described above. Each of the 40 specimen pairs was tested to failure and load vs.

extension curves were obtained. The average maximum load at yield, zero slope on the curve, for each sample set was obtained and then plotted versus the intended angle θ and tooth thickness $2{*}R$ (Figure 48 & Figure 49).

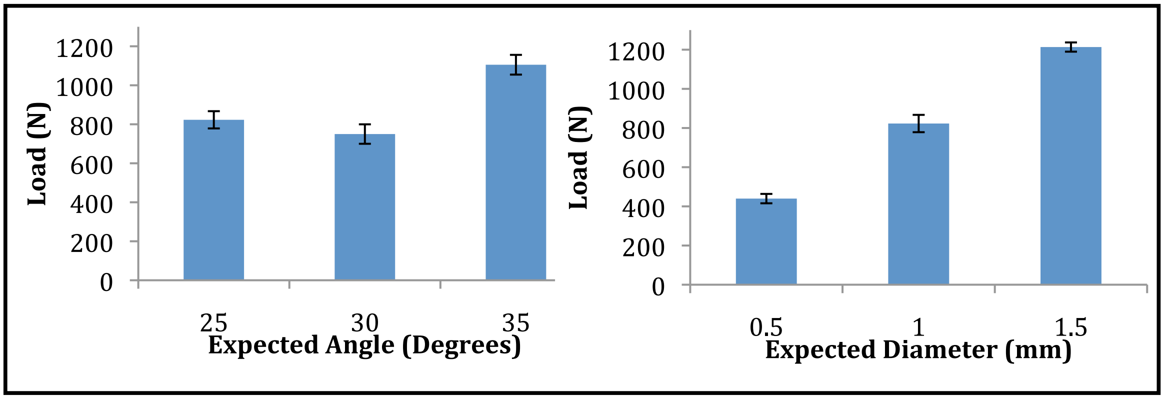

Figure 48: Load Capacity of the Redesign Ratchet vs. Angle (Left) and Fillet Diameter (Right)

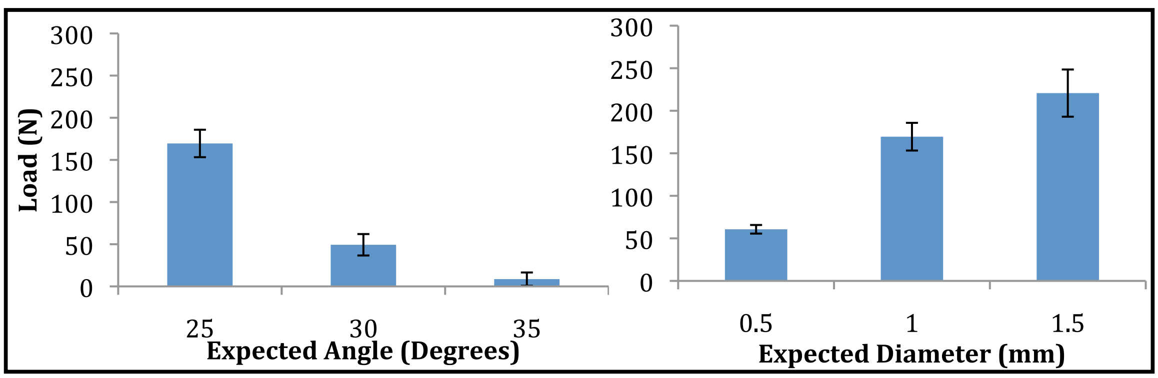

Figure 49: Load Capacity of the Rotated Redesign Ratchet vs. Angle (Left) and Fillet Diameter (Right)

All of the redesigned ratchet specimen pairs failed at more than nine times the maximum anticipated load of 47.5 N for the intended application of these fasteners. However, not all of the rotated redesign ratchet specimen pairs failed at loads above anticipated. The 30° and 35° specimens failed on average at or below the anticipated load of 45.7 N.

The final area of testing includes the further verification of the FEM developed previously. This was accomplished by again comparing the load vs. extension curves generated by the FEA and the experimental results for the redesigned ratchet fastener specimens. As before, mean dimension values obtained during the geometric accuracy verification process were used in the FEM and extension and von Mises stresses were obtain at four different load values, one at yield and three others equally spaced along the linear elastic range of the curve. Material properties used were the Nylon 11 material properties for tensile strength (48.43 MPa), modulus of elasticity (1622 MPa), and density (.97 g/cm^3) determined from tensile bars included in the build tested according to ASTM D638 (Table 17). The Poisson's ratio of .4145 used was the average ratio value available from CES EduPack Software produced by GRANTA (*PA,* 2008). Figure 50 and Figure 51 show the resulting theoretical and experimental load vs. extension curves.

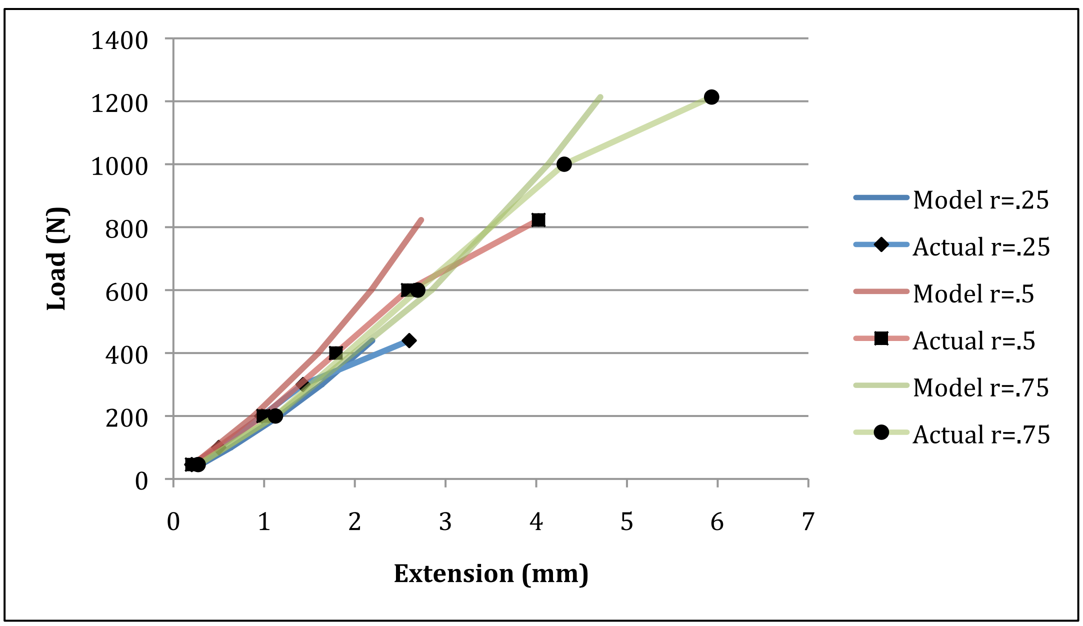

Figure 50: Comparison of Redesigned Ratchet Theoretical Strength Model to Experimental Data - Range of Fillet Radii (0.25, 0.5, and 0.75 mm)

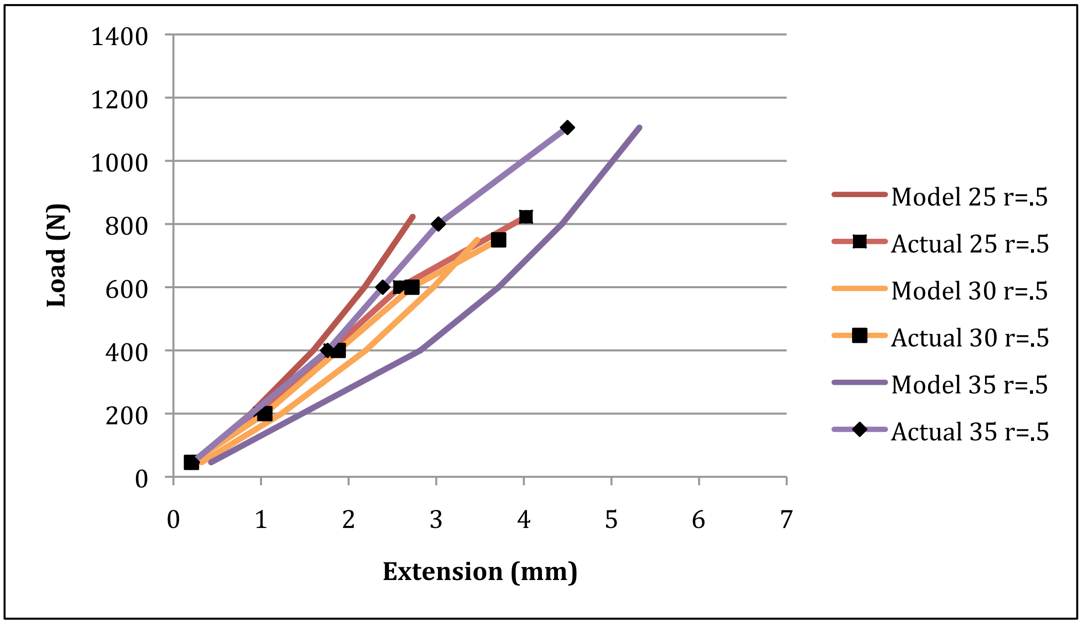

Figure 51: Comparison of Redesigned Ratchet Theoretical Strength Model to Experimental Data - Range of Internal Tooth Angles (25, 30, and 35 deg)

The relative difference of the model curves from the experimental data is presented in Figure 52. Again, a similar trend where the relative difference increases as the specimens begin to yield is seen.

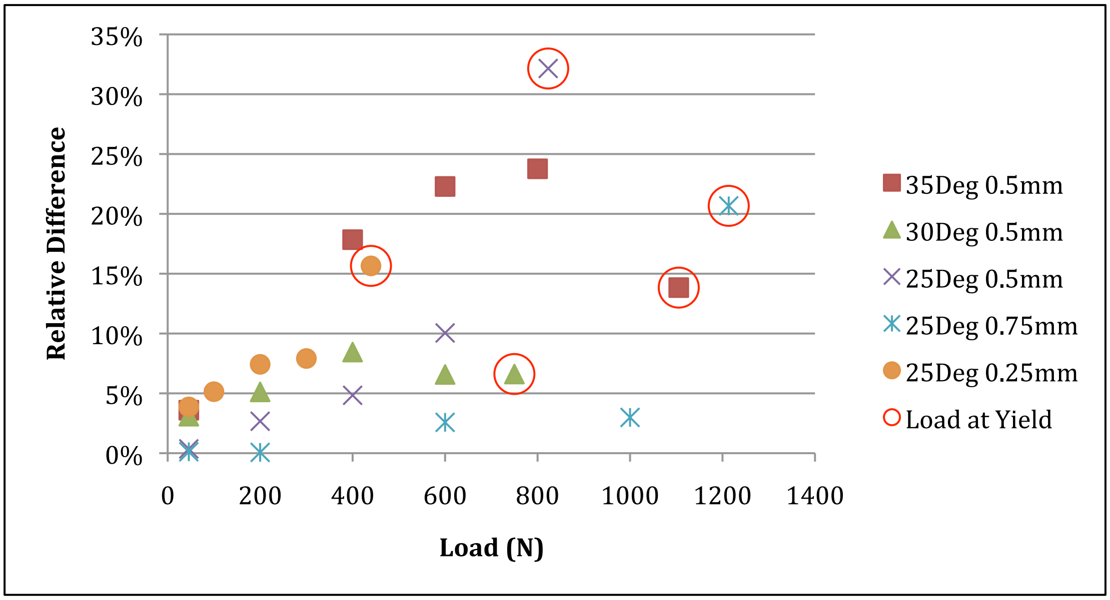

Figure 52: Relative Percent Difference of Redesigned Ratchet FEM Results from Experimental (Load at yield circled)

The comparison of the experimental data to the theoretical model for the rotated ratchet samples however, did not demonstrate as strong an agreement. For example, the relative difference between the theoretical and actual curves for the 25° specimen with the fillet of .75 mm is 22% at 50 N and 79% at maximum load (Figure 53). The other specimen geometries exhibited even larger relative differences. The possible cause for this is discussed further in the next chapter.

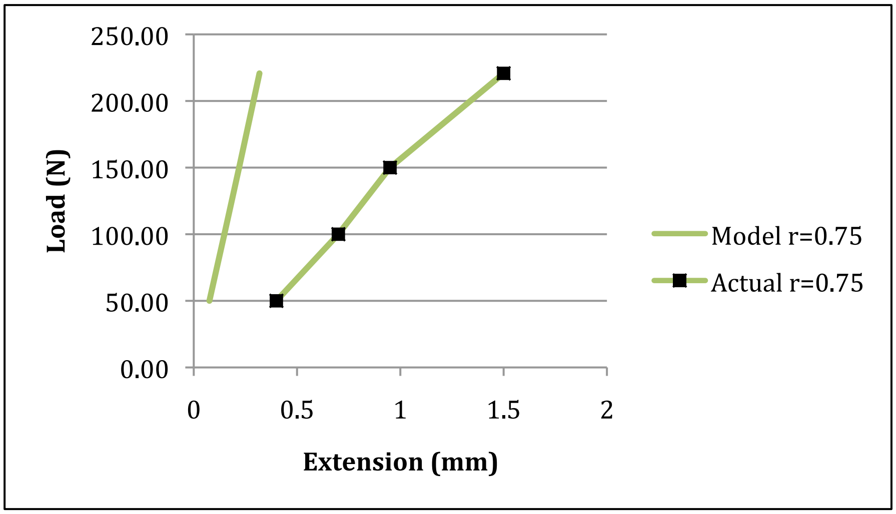

Figure 53: Comparison of Rotated Ratchet Theoretical and Experimental Results

CONCLUSION

The two design iterations each for the threaded and ratchet style testing specimens presented are based on the development of design tools for use in the future inclusion of such fastening mechanisms in a full socket design. Further discussion of the results obtained from the analysis and their implications are presented in the following chapter.

Chapter 7: *Discussion*

This study has shown that both threaded and ratchet style fasteners can be manufactured using SLS. The parts manufactured using SLS were functional and the theoretical models developed for the fasteners show promise for use in the design of these fasteners in future adjustable socket designs.

GEOMETRIC ACCURACY

Preliminary SLS builds demonstrated growth issues and were used to determine minimum feature and clearance sizes. The final iteration of the ratchet and threaded fastener test specimens show decreased growth and shrinkage as compared to the first specimen build. However, as the geometric accuracy of the second build of the fastener testing specimens demonstrated, still further refinement of the solid models is needed to obtain even tighter dimensional tolerances.

The pitch, minor diameter, and thread thickness of the threaded specimens were all on average less than 5% different from the nominal dimensions. The thread thickness, where the greatest discrepancy still resides, decreased from 24% in the first iteration. This is promising, however, as some of the threaded specimens still varied as much as 10.75% from the nominal dimension, some adjustments to reduce the variability in this dimension are required.

Similarly, the tooth height and overall length of the ratchet specimens were all less than 5% different from the nominal size. The tooth thickness, however, still experienced 28% growth. This contrasts with the initial iteration of the ratchet specimens where the tooth thickness was on average 30% smaller than the intended size. The rotated ratchet specimens demonstrated a growth pattern similar to the regular ratchet specimen design. Again, the tooth height and overall length of the rotated ratchet specimens were less than 5% different from the nominal dimensions. The tooth thickness is again experiencing greater growth at an average of 13% increase from the intended value. Of particular note, the second iteration of specimens was able to achieve full tooth length for all of the specimens as all features were above the minimum feature size, unlike the 1.0 mm tooth thickness ratchet specimens from the first iteration.

Of the dimensions with larger variation from the expected value, those with smaller thicknesses, such as the tooth and thread thicknesses, are more common. Two possible reasons for this have been theorized. First, as these features are often only one or two times the minimum feature size, the SLS manufacturing process could be experiencing difficulties sintering these smaller features. Second, this could be a result of the limitations of using calipers to measure the thickness of such small features on a specimen that is manufactured using a layer based additive manufacturing process. Being layer based, surface finishes on SLS parts become proportionally less smooth on smaller feature surfaces as defects take up a greater percentage of the surface area. Therefore these defects in the surface could be giving false measurement readings.

Impacts of growth and shrinkage varied for the threaded and ratchet fastener specimens. Due to the reduced growth on the second iteration of the threaded fasteners, specimen pairs had looser fits. Therefore further optimization of the tooth clearances could be obtained once stable build results are achieved. For the ratchet specimens, tooth thicknesses still had growth issues and therefore parts were still not fully contacting along the crease as designed (Figure 54). This means that the attempt to concentrate load at the base of the tooth did not occur.

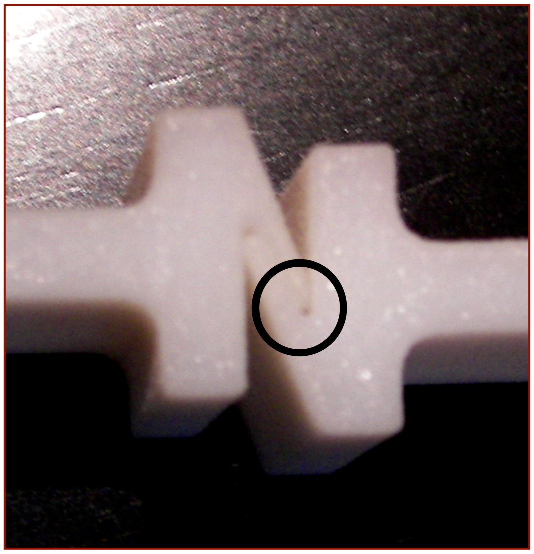

Figure 54: Gap in Teeth of Mating Ratchet Specimens

In addition to growth, curl was also encountered in several of the ratchet specimens from the initial build. Less curl was encountered in the second specimen build. The exact cause of the decrease in curl is currently unknown though an increase in the part bed temperature by 1° C and a longer cooling time in the inert build chamber were implemented in the second build. Curl can be further eliminated with improvement of build and part parameter setting selection based on whether the curl is occurring during or after the build process.

Further builds are needed to understand the causes for the differences between manufactured feature dimensions and the expected nominal dimensions. In addition, curl was also encountered in several of the ratchet specimens. Curl can be eliminated with further improvement of build and part parameter setting selection. The impacts of these growth and shrinkage issues, however, are minimized in the theoretical model by using the actual dimensions resulting from the build during analysis rather than the nominal dimensions.

LOAD CAPACITY

In spite of the growth issues, both of these fastener test specimen designs exceeded the load capacity required for their respective applications. The redesigned threaded specimens sustained a load that exceeded the anticipated load of 2500 N. Some decrease in the maximum load was anticipated as these specimens were designed to fail at 3000 N rather than 4000 N as in the first iteration. However, it is questionable whether the failure of the specimens was in the threads or simply in the tabs. As seen in Figure 55, the smaller surface area in contact with the grips tended to yield before the threads.

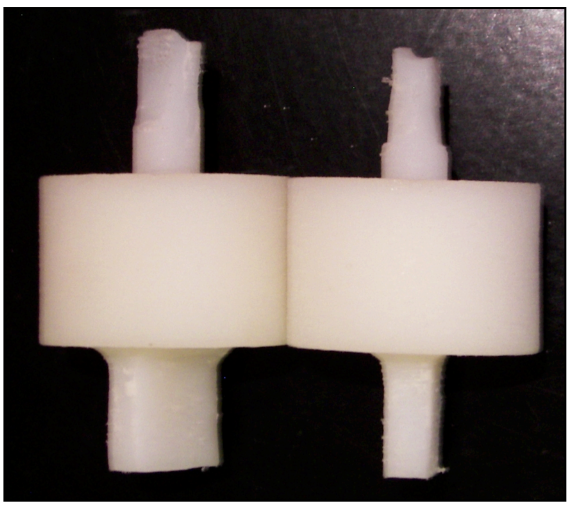

Figure 55: Deformation of Threaded Specimen Pull Tabs

Since the threaded specimens are continuing to yield in the tabs of the samples, further improvements are needed to strengthen these tabs so that the load is concentrated on the threads. This will likely require increasing the surface area in contact with the tensile testing machine clamps. These specimens however are scaled versions of those that might be included in a height adjustment mechanism. The ability of the threaded fasteners to withstand 2500 N indicates that smaller pitches can be utilized in a full-scale application and that an appropriate factor of safety is achievable.

As highlighted in Figure 56, some of the load vs. extension curves have an initial flat section and do not begin to show loading until 0.5 to 0.75 mm extension. This is due to the fact that the specimens are unloaded at the start of testing and the tensile machine therefore initially travels without loading the specimen through a distance approximately equal to the clearance between the threads. A tighter fitting thread or a preload would therefore reduce this initial unloaded section.

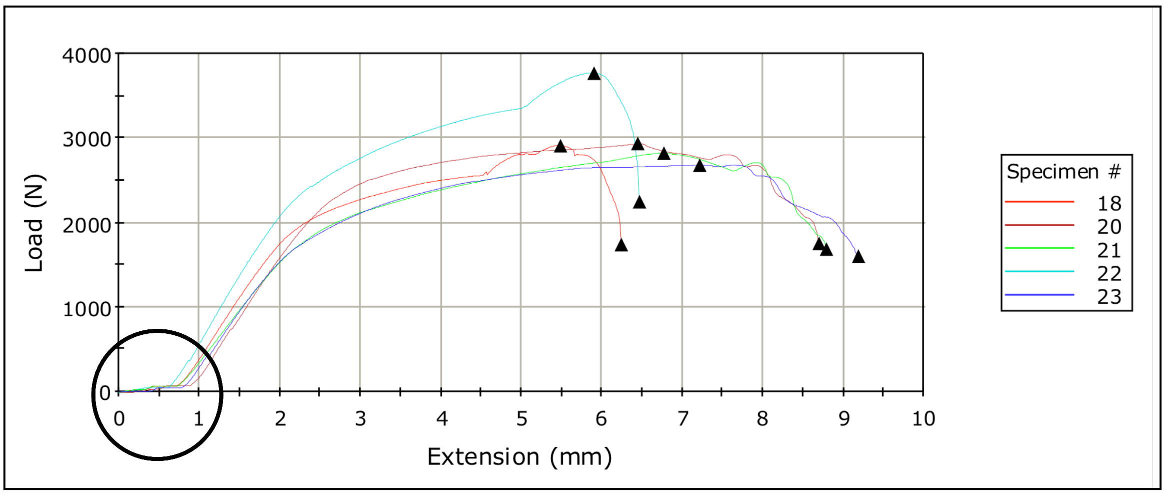

Figure 56: Example of Initial Unloaded Region of Threaded Specimen Load vs. Extension Curve

For the ratchet fasteners, the average load achieved by all specimens in the second iteration of the design, 866 N, was higher than the original design, 346 N. This appears to support the addition of fillets and larger tooth thicknesses for increasing the strength of the mechanisms. This change is not likely due to the differences in the quality of the builds obtained as the tensile strength varied from 47.5 to 48.7 MPa and 49.1 to 49.0 MPa in the two orthogonal directions of the horizontal plane of the build chamber respectively for the subsequent build. The maximum loads achieved by the final specimen designs ranged from 9 to 25 times larger than the anticipated load of 47.5 N for the anticipated socket wall implementation. The strength of these ratchet mechanisms therefore implies that the use of hook style ratcheting fasteners in the full adjustable socket design in a similar loading condition is feasible.

Upon comparison with trends in other load data, the maximum loading results for the 1.00 mm tooth thickness from the initial iteration of the ratchet fastener specimens are suspicious. The tooth did not completely sinter, however, these specimens had the greatest load capacity. This is likely the result of the load not being concentrated on the tooth itself but at the base of the tooth. This in turn prompted a redesign of the specimens such that it helped to concentrate the load at the base of the tooth. To this end, a fillet with matching radii R was added to the crease as well as the point of the tooth in the second specimen design iteration.

Due to the design of the tensile testing machine, the maximum loading capacity at yield of the rotated ratchet specimens, unlike the normal orientation specimens, could not be measured. This is likely due to looseness of the clamps, which could be displaced as much as 5 mm horizontally at the point of contact of the testing specimens. With tooth heights of 3-5 mm, the specimens only maintained contact as long as there was sufficient friction on the contacting surfaces. Instead, the resistive force due to friction was measured. Therefore the load results are only indicative of which specimen design, due to the tooth thickness and angle, had the greatest friction force to resist motion of the contacting tooth surfaces. Based on these results, the 25° internal tooth angle supported the greatest load prior to fully disengaging. This suggests the use of smaller angles in the ratchet specimens for the sake of reducing the potential for unhooking due to a load direction different from the primary loading orientation. In addition, the larger fillet radii, and therefore larger tooth thicknesses, also contributed to a greater load before failure. This is likely due to the increased bending strength of the tooth. These results, however, do not reflect the actual load case that would include an increased normal force, and therefore friction force, that would be caused by the primary loading orientation acting simultaneously on the ratchet specimen. The maximum obtained load of 220 N is therefore an estimate of the force necessary to cause the ratchet to unhook in the weakest loading condition when there is no load in the orthogonal direction.

MODEL ACCURACY

In addition to the geometric accuracy and load capacity analysis of the fastener testing specimens, the accuracy of the theoretical models is a final focus of this study. Due to the failure of some of the threaded specimens in the tabs rather than in the actual specimen threads, the theoretical model is still not fully verified. Sixty percent of the tested specimen pairs failed as predicted by the model for the second iteration of specimens. As all of the specimens sustained a load greater than the 2500 N load expected in an actual application, these specimens do indicate that smaller pitches can be utilized in a full-scale application. This model therefore does provide a conservative estimate of the strength of the threads. Further testing with redesigned tabs for insertion in the tensile testing machine clamps is needed.

Based on the comparison of the theoretical model results with the experimental data collected, the ratchet theoretical model is only valid in the linear elastic range. Errors between the empirical and theoretical results range were less than 10% for most cases in this region. As this is the target for which a fastener would be designed, using this model when designing in this region will ensure that there will be a lower occurrence of failure or yielding of the fastener during use.

APPLICATION OF RESULTS

These theoretical models were developed to determine the feasibility of including fastening mechanisms in a complete adaptable socket design for pediatric patients in developing countries. As both models have shown promise for this use, several options for implementation of these fastener designs are possible. The volumetric adjustment mechanism concepts generated and selected in Chapters 4 and 5 that utilize these fastener mechanisms therefore can be deemed feasible for implementation in a full socket design. The most likely use of the threaded fastener is allowing longitudinal height adjustment of the pylon and its connecting/adjustment mechanism. As described in Chapter 4, the Threaded Wall longitudinal adjustment concept is a viable implementation of this fastening mechanism for ensuring the functionality of this volume adjustment concept (Figure 57).

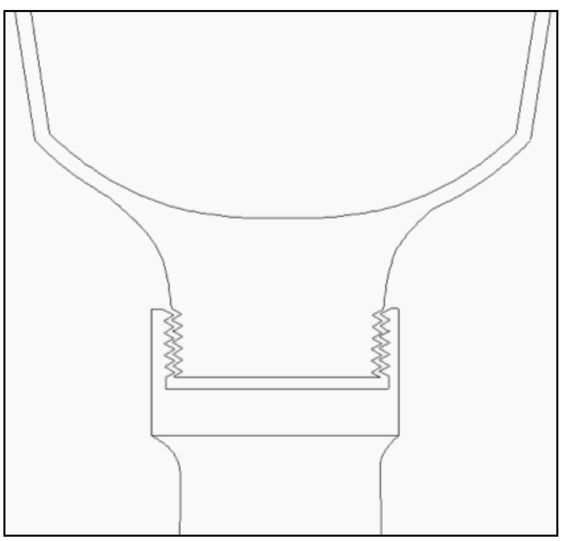

Figure 57: Possible Threaded Fastener Implementation

Similarly, the ratchet mechanisms designed could be implemented in a radial adjustment mechanism like the Pipe Clamp concept that would be secured using this ratcheting fastener mechanism (Figure 11). Removal of the ratchet fastener can be aided by the addition of a release edge that allows the required leverage for the force required to disengage the latched teeth (Figure 58).

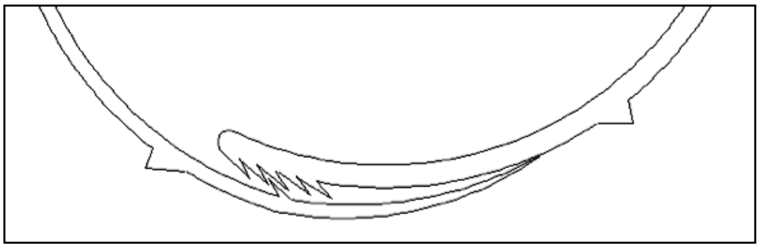

Figure 58: Possible Ratchet Fastener Implementation

As the actual implementation of the fastener mechanisms will likely not take on a form exactly like those of the testing specimens, the theoretical models developed allow adjustment of the design to the particular application.

Chapter 8: *Conclusion*

With the great need for properly fitting prosthetic sockets, for pediatric as well as adult lower limb amputees, this research focused on designing a new prosthetic socket that addresses a possible solution to this need. Due to the relatively large amount of volumetric change inherent in children during the natural maturation process, this research seeks to provide a socket that is adjustable to both the radial and longitudinal changes in the volume of the residual limb. With an emphasis on transtibial prosthetic socket designs, a variety of design concepts intended to fulfill the primary functions identified for an appropriate design were generated. These functions include: accommodation of both radial and longitudinal volumetric changes in the residual limb, ability to interface with a socket suspension system and other prosthetic components, user safety and aesthetics, and methods to combine mechanisms designed for each function above. Using concept generation techniques modified from those presented by Otto and Wood (2000), plausible designs were generated and the most promising were selected based on criteria derived from customer needs analysis consisting of personal experience, interviews, and reviewing literature. Before a full socket design can be fully realized, however, a feasibility study of the fastener mechanisms was completed. This feasibility study was necessary since these mechanisms dictate the overall strength and functionality of the final socket. Therefore, this research focused on the design and validation of theoretical models for two fastener mechanisms, the threaded and ratchet style.

Based on design analysis and theoretical models validating the two fastener mechanisms, the designs are ready for implementation in a final socket design. The ratchet theoretical model adequately predicts extension based on input loads in the elastic range of the design curve. The deviation of the theoretical model from the experimental data is less than 10% in this elastic region of the load vs. extension curve. These specimens continue to sustain loads more than nine times the anticipated load during use. This therefore suggests that the ratchet fastener model can be confidently applied to the socket design problem at hand. With this working model, further investigations can be made into the integrity of the ratchet design in other loading conditions and to determine whether the fastener will bind under the loads.

The threaded fastener theoretical model has not been fully verified as the specimens have not consistently yielded in the threads, though they do fail close to the intended failure load. Those that have failed in the threads, 60% of those tested, did fail close to the anticipated 3000 N. Further specimen redesigns are needed to fully verify this theoretical model. However, the threaded specimens that have been manufactured do provide some information about the strength of threaded fasteners. As they have sustained the anticipated load at even a scaled size, their implementation in a full adaptable socket design is feasible. Prediction of their strength via a theoretical model, however, has not been fully demonstrated, but the model does give a conservative estimate of where the specimens may fail that can be used in guiding inclusion of these fastener mechanisms in a socket design. There are possible improvements that can be made to the threaded specimens to help ensure failure of the threads rather than the tabs. Increasing the surface area of the tabs in contact with the tensile testing machine clamps is the first recommended step as the thickness of the tabs is limited by the gap in the grips.

It would also be of benefit to consider other loading conditions in addition to axial loading. Axial loading is likely the primary loading condition base on the maximum loading determined during plyometric jumps (McKay et al., 2005). However, a bending moment could be experienced at the connection to the socket due to loads being applied sat the toe of the prosthetic foot that would behave as a moment arm. This bending moment could cause binding of the threads that is not encountered during axial loading and therefore is an area for further research.

In addition to redesigning the tabs of the threaded testing specimens, the next steps in this research include refinement of the testing specimens, additional theoretical models, fatigue analysis, and utilizing the fasteners in combination with the generated socket concepts to develop a final socket design. As growth was still occurring, though not greatly impacting the results, in the second iteration of the manufactured testing specimens, additional optimization of the SLS manufacturing method is needed to hone the dimensional tolerances of the sintered parts. The ratchet specimens require optimization of the surface area needed to resist unhooking during slip as well as to help concentrate load at the base of the tooth where it is thickest. As the rotated ratchet specimens were not preloaded during testing, a more accurate measure of the force needed to disengage the hook could be obtained with a preload equal to the tension in the perpendicular direction. In addition, the theoretical model for the threaded specimens only accounts for an axial load. As this is only one of the possible loading conditions, considerations should be made for a bending moment being applied to the load. Furthermore, fatigue characteristics of these fastening mechanisms remains to be determined as these specimens were loaded under static conditions until failure and have not been cycled at the anticipated loads.

Threaded and ratchet style fasteners have been successfully manufactured using SLS. These specimens, though currently needing further adjustment for growth, are capable of sustaining loads greater than those expected in their respective applications. In addition, theoretical models have been presented and preliminary validation has been provided. As a result of this work, threaded and ratchet style fasteners are shown to be feasible methods for incorporating radial and longitudinal volumetric change methods into a single volume compensation socket design for pediatric patients in developing countries.

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Vita

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